Newport Medical Instruments, Inc.

Newport HT70 Series Ventilator

Service Manual

SERHT70-2 Rev. B

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Section 1:
Introduction

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Brief Device Description

The Newport HT70 family of ventilators are state of the art ventilators that combine ruggedness, ease of use and clinical proficiency with exceptional mobility to provide ventilatory support for infant, pediatric and adult patients in emergency care, transport, subacute care and home care applications. It is also ideal for emergency preparedness applications.

The compact, lightweight HT70 ventilator is built for hard work with a durable polymer exterior and robust overall design that stands up to harsh environments.

The HT70 Ventilator defines ease of use with all essential controls at your fingertips using a simple membrane button and touch screen combination. There are no complicated menus or difficult sequences to follow in order to make necessary adjustments for common operations.

A three-tiered management domain system makes it very easy for caregivers to manage all controls while providing quick access to the more essential elements in transport situations and significantly enhanced safety and simplicity in the homecare environment.

Sophisticated Clinical Capabilities

In addition to its durability and ease of use, the HT70 ventilator offers the complete array of clinical capabilities needed for managing patients.

The twin micro-piston pump's ability to deliver a variable flow enables the HT70 to provide a full range of operating modes and breath types with servo-controlled, leak-compensated PEEP. Leak compensation helps to improve triggering and avoid auto-triggering when a leak is present. The HT70 may be used with an endotracheal tube, tracheal tube, face mask, nasal mask or prongs, or mouthpiece.

There are 3 models for the HT70 series of ventilators:

HT70S	HT70 Basic for use when Pressure Support is not needed.
HT70	HT70 Classic, adds Pressure Support and related parameters and Trends screen
HT70PM	HT70 Plus, adds on-airway flow sensor option with graphics, flow trigger and exhaled volumes

The HT70 Basic and Classic models provide monitoring of inspiratory tidal volume (every breath), inspiratory minute volume, total respiratory rate, peak pressure, mean pressure and baseline (PEEP) pressure. Real-time patient circuit pressure is displayed at all times

on the airway pressure gauge on the face panel. A comprehensive alarm system is built-in to alert the user to violations of user-set or ventilator safety limits. An optional built-in oxygen sensor allows monitoring of O_2 with high and low O_2 alarms.

The HT70 Plus model adds an on-airway flow sensor with onscreen graphics, exhaled tidal and minute volume monitoring/alarms, and flow trigger. This manual describes the HT70 Plus model and will denote features that are not available on the HT70 and HT70S models.

Gas delivery to the patient may be enriched with oxygen (0.21-1.00) using either the optional Air Oxygen Entrainment (50 psi) Mixer or optional Low Flow Oxygen Reservoir.

Exceptional Mobility

The ventilator's unique design provides maximum mobility and safety for short or long distance transport of critically ill patients and also for patients who are going about their normal activities of daily life. This exceptional mobility is derived from two sources: Newport's patented, power conserving dual-micro-piston technology which eliminates the need for an external compressed gas source, and the Internal Dual Battery System which allows virtually continuous use from battery power through hot-swappable technology.

The HT70's micro-pistons use a fraction of the power that is consumed by turbines and blowers. This enables longer battery use time. Our patented system also uses considerably less supplemental oxygen than turbine or blower systems, again improving mobility for transport or homecare use. The superior technology of our micro-piston system over the turbine and blower systems allow the HT70 to ventilate safely over a wide range of environmental conditions and altitudes.

The HT70's twin micro-piston internal pump is made of mechanically moving components. As with any other gas delivery system made of moving components, it may emit a minor level of noise during operation. This is not a malfunction and does not affect the performance of the ventilator.

The Internal Dual Battery System consists of two independent but coordinated lithium ion batteries, the Power Pac battery, located on the back of the ventilator and the Backup Battery inside the ventilator. The Internal Dual Battery System can provide up to 10 hours of operation at standard settings when new and fully charged. This system assures continued support during transport, daily activities or power outages.

The detachable Power Pac is 'hot-swappable'. That is, if more battery time is needed, a depleted Power Pac can easily be removed from the back of the HT70 and replaced with a recharged Power Pac without interrupting ventilation. No tools are needed. The secondary Backup Battery maintains operation without interruption when the Power Pac is swapped out and also provides a minimum of 30 minutes of full operation when all other power sources are depleted. The Power Pac weighs two pounds and is charged anytime the ventilator is connected to an external power source (AC or DC). It can also be charged separately.

The HT70 may be operated from a variety of AC (100-240 VAC @ 50 / 60 Hz) or DC (12-24 VDC) external power sources or from the Internal Dual Battery System. The optional DC Auto Lighter Power Adapter accessory enables connection to an automobile-type DC outlet. Any time the ventilator is connected to external power, both batteries in the Internal Dual Battery System are charging, whether or not the ventilator is in use.

Travel Certified

The HT70 has been tested for and meets requirements for use in helicopter and fixed wing transport and for use on commercial airlines. Before traveling, be sure to speak with your airline representative about their particular concerns and clear all of your equipment with them well before your departure. The labeling that the FAA requires to be on the ventilator is located on the bottom of the HT70.

Intended Use

Newport HT70 family of ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or noninvasive interfaces.

Specifically, the Newport HT70 family of ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs) in hospital, sub-acute, emergency department, and home care environments as well as for transport and emergency response applications.

NOTE: Federal law (US) restricts sale by or on the order of a physician.

Ventilator Configurations

Newport Medical offers five configurations for the 3 models in the HT70 family of ventilators. See Table 1. In addition, the front control panel labeling is available in various languages and regional power cords, i.e. North American, European, etc., can be specified. See your Newport Medical Representative for details.

Table 1

Part Number	Description	Distinguishing Features
HT70PM	HT70 Plus	Full featured with Flow sensor, graphics and built-in oxygen monitor with alarms. Compatible with optional plug and play pulse oximeter
HT70	HT70, w/o Oxygen Sensor	Classic features No built-in oxygen monitor
HT70M	HT70, with Oxygen Sensor	Classic features Includes built-in oxygen monitor with alarms
HT70S	HT70, Basic w/o Oxygen Sensor	Classic features except: • No Pressure Support or Pressure Support parameters • No Trends • No built-in oxygen monitor
HT70SM	HT70, Basic with Oxygen Sensor	Classic features except: • No Pressure Support or Pressure Support parameters • No Trends Includes built-in oxygen monitor with alarms

Warnings, Cautions, and Notes

Please review all WARNINGS and Cautions outlined in this manual before operating the ventilator.

Use of the product requires full understanding and strict observation of all sections of these instructions. The equipment is only to be used for the purposes specified under Intended Use and in conjunction with appropriate patient observation and monitoring. Observe all WARNINGS and Cautions that appear in this manual and on equipment labels.

WARNING A warning describes a condition that can cause injury.

Caution: A caution describes a condition that can cause damage to equipment.

NOTE: A note emphasizes information that is important or convenient.

General Notes

The Newport HT70 has been designed to accommodate connectivity with nurse call/monitoring systems. Because it is not possible to anticipate every configuration of hardware and software associated with nurse call/monitoring system, it is the user's responsibility to confirm proper functionality of the system when used in conjunction with the HT70. Verification of alarms, alerts and patient data transmissions is required. If the system performance is not as expected, contact Newport Medical Technical Support for assistance troubleshooting the set-up. Do not use the HT70 ventilator with a nurse call/monitoring system until the functionality of the ventilator/ system combination has been confirmed.

General Cautions

Do not place liquids on or near the ventilator.

Damage can occur if the HT70 is exposed to extreme temperatures. Do not store the HT70 in areas where it may be exposed to temperatures below -40° C (-40° F) or above 65° C (149° F).

To avoid the risk of electric shock, the ventilator should not be opened by anyone other than an approved service provider.

General Warnings

The design of the HT70 ventilator, the Operating and Service manuals, and the labeling on the ventilator take into consideration that the purchase and use of the equipment is restricted to trained professionals, and that certain inherent characteristics of the ventilator are known to the operator. Instructions, warnings and caution statements are therefore limited to the specifics of the HT70.

This manual excludes references to various hazards which are obvious to medical professionals and operators of this equipment including consequences of product misuse, and potential adverse effects in patients with abnormal conditions.

Transport of patients with the HT70 requires that medical staff have a good working knowledge of the ventilator's use and

problem resolution. Proper emergency backup equipment must be immediately available during transport.

Product modification or misuse can be dangerous. Newport Medical Instruments, Inc. disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this ventilator with other products, whether supplied by Newport or by other manufacturers, unless such a combination has been specifically endorsed by Newport Medical. There is a risk of explosion if used in the presence of flammable anesthetics.

A patient connected to a ventilator requires the constant attention of trained caregivers to the patient's condition.

Ventilator alarms are a critical element in the safety net of patient care. It is extremely important for patient safety that caregivers immediately identify and correct alarm violations.

Always have an alternate power source and means of ventilation available when the ventilator is in use so that they are easy to access in case of a mechanical or system problem.

If a fault is detected in the ventilator and its life support functions are in doubt, immediately discontinue use; use an alternative method of ventilation until the fault has been corrected. Contact your service provider immediately.

Do not block the Emergency Gas Intake (on the bottom panel) or the Fresh Gas Intake Port (on the right side panel).

Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and/or a capnograph) when the HT70 Ventilator is in use on a patient.

The optional Air/Oxygen Entrainment Mixer and Low Flow Oxygen Reservoir are designed to operate with medical grade oxygen.

Ensure that the oxygen source is not empty before and during the use of the optional Air/Oxygen Entrainment Mixer or Low Flow Oxygen Reservoir.

When the optional Air/Oxygen Entrainment Mixer is secured in place, ensure that the oxygen supply is enabled prior to powering the HT70 on to avoid putting stress on the internal pump and compromising gas delivery to the patient.

Calibrated oxygen monitoring at clinically appropriate levels is required for patient safety when supplemental oxygen is in use. The optional built-in oxygen sensor on the HT70 allows High and Low O_2 alarms to be enabled which can be used to assure proper oxygen delivery.

Always plug the HT70 into an external power supply source whenever it is available, even when HT70 is not in use, to keep the Internal Dual Battery System fully charged and to ensure best battery performance. Check battery capacity on the front panel before detaching from external power.

When installing a replacement Power Pac during battery operation, always ensure that the charge level LED on the replacement pack is green, indicating 90% or higher charge level.

Always ensure that the green External Power LED lights after connecting the ventilator to an external AC or DC power source.

To maintain grounding integrity when using AC power, only connect to properly grounded receptacles.

Use only the Newport supplied AC Power Supply (p/n PWR3204P) with the HT70 ventilator and HT70 Power Pac (p/n BAT3271A).

Always disconnect the external power supply prior to servicing.

After servicing the HT70, it must pass the Operational Verification Procedure (OVP) before it is returned to patient use. See section 6 of the HT70 Service Manual.

Do not use electrically conductive breathing circuits. Always use clean and dry breathing circuits.

Always use a clean, dry filter in the following locations: a standard bacteria filter on the gas output, a prox line (bacteria) filter on the proximal pressure tubing and an intake (bacteria) filter behind the filter cover.

Adding attachments or other components or sub-assemblies to the ventilator breathing circuit system can increase the patient's work of breathing and/or add resistance to patient exhalation.

Always ensure that the audible alarm loudness level is set at a volume that can be heard by the caregiver. Do not use the ventilator in an environment where audible alarms cannot be heard by the caregivers.

The functioning of this machine may be adversely affected by the operation of other medical equipment, such as high frequency surgical(diathermy) equipment, defibrillators or short-wave therapy equipment in the vicinity.

This device has undergone EMC testing and found to be in conformance with IEC 60601-1-2:2001 and meets the requirement of CISPR11:2004 (Class B), IEC 61000-3-2:2006, and IEC 61000-3-3:1955 + A1:2001 + A2:2005. These requirements are designed to provide reasonable protection against harmful interference in a typical medical installation, as well as in homecare environments. The equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures;

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the devices(s) is connected.
- Consult the manufacturer or field service technician for help.

Copyright Information

Section 2:

Specifications

Section 2:
Specifications

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Front Panel Buttons - Symbols Version	
	Accept
	Cancel
	Alarm Silence Reset / LED
	Breath Delivery Indicator
	Brightness
	Device Alert LED
	External Power LED
	Manual Inflation
	Up/Down Arrow

Miscellaneous Reference Symbols	
	Manufacturer Name and Address
EC REP	Authorized Representative in the European community
O	Main Power Off / On (momentary switch)
↓	Low (Paw or Min Vol) alarm
↑	High (Paw, Min Vol or RR) alarm
	Attention, see instructions for use
	Equipotentiality
	Applied Parts Type BF
	Brightness control
	Alarm Silence
▲ / ▼	Up / Down arrow
	Federal law (US) restricts sale by or on the order of a physician
	Meets FAA requirements in RTCA standard, DO160, sec 21 category M for use in all stages of air travel, including takeoff and landing.
	Single patient use

Controls/Monitors		
Controls / Monitors	**Range / Selection**	**Resolution**
MODE (Pressure or Volume Control)	A/CMV	
	SIMV	
	SPONT	
Breath type (mandatory)	Pressure Control or Volume Control	
NIV (Non Invasive ventilation)	On or Off, When On, allows ↓Min Vol Alarm to be set to Off, ↓P Alarm to be to be set 1 cmH_2O/mbar above PEEP and allows adjustment of bias flow during PEEP	
VT (Tidal Volume)	50 to 2,200 mL, ATPS, ± 10%	1.0 mL
PC (Pressure Control)	5 to 60 cmH_2O / mbar	1.0 cmH_2O/mbar
Flow	6 to 100 L/min	1.0 L/min
i time (Inspiratory Time)	0.1 to 3.0 sec	0.1 sec
RR (Respiratory Rate)	1 to 99 b/min	1.0 b/min
P trig (Sensitivity)	–9.9 to 0 cmH_2O / mbar, pressure triggering	0.1 cmH_2O/mbar
Flow trig (Sensitivity)	0.1 to 10 L/min	0.1 L/min
PEEP/CPAP	0 to 30 cmH_2O / mbar	1.0 cmH_2O/mbar
PS (Pressure Support)*	0 to 60 cmH_2O / mbar above baseline pressure, limited to PEEP + PS ≤ 60 cmH_2O / mbar	1.0 cmH_2O/mbar

* Not available on the HT70S models

Controls / Monitors	Range / Selection	Resolution
I:E Ratio	1:99 to 3:1	0.1 for 9.9:1 to 1:99 and 1 for 99:1 to 1:99
Airway Pressure Gauge	–10 to 100 cmH_2O / –10 to 98 mbar includes indicator bars to show low and high PAW alarm limits	
O_2 Sensor	Enabled or Disabled When Enabled, high and low O_2 alarms are active and O_2 Cylinder Time Calculator is available	
PS Max i time*	0.1 - 3.0 sec	0.1 sec
PS % Exp Threshold*	5 - 85%	5
Slope Rise	1 -10 (1 is slowest)	1
Flow Wave Pattern	Square or Descending	
Bias Flow	0 L/min - PEEP Off 7 L/min - PEEP On 3-30 L/min - PEEP + NIV On	1
AutoLock function	Enabled/ Disabled	
AutoLock icon	Touch for 3 seconds to unlock buttons if AutoLock is Enabled in *Utility* screen. When Lock is on screen, all controls are locked except Alarm Silence Reset, manual inflation and Brightness control.	
O_2 Cylinder Data	Size: D, E, H, M, K, 100 L & 150 L Cylinder Pressure: 300 to 2450 psi or 25 to 175 ATM or 2,000 to 17,000 kPa Units: psi or ATM or kPa O2 Cylinder Monitor; Enabled/Disabled.	
Altitude	-1,000 to 10,000 feet, -1,000 to 10,000 meters (with Flow Sensor use)	
BUV Settings	Minimum RR: 8 to 30 b/min Rate Factor: 1.1 to 1.8 SPONT Delta P: 5 to 20 cmH_2O/mbar SPONT i-time: 0.4 to 2.0 s	
Monitor Data Selections		
Minute Volume	0.01 L to 80.0 L	0.01 L
Insp./Exp. Tidal Volume	0.01 L to 3.0 L	0.01 L
RR total	0 to 200 b/min	1 b/min

* Not available on the HT70S models

Monitor Data Selections		
P Peak	0 to 100 cmH_2O /mbar	1 cmH_2O/mbar
P Mean	0 to 100 cmH_2O /mbar	1 cmH_2O/mbar
P Base (PEEP)	0 to 100 cmH_2O /mbar	1 cmH_2O/mbar
(Peak) Flow	5 to 150 L/min	0.1 L/min
O_2 Cylinder time	hours / min	15 minutes
Battery time	hours / min	15 minutes
O_2% (optional)	21 to 100	1%
I:E Ratio	1:99.0 to 3.0:1	0.1 (9.9:1 to 1:9.9) 1.0 (99:1 to 1:99)

Front Panel Membrane Buttons and Indicators	
Cancel	Press front panel button to cancel any touchscreen settings changes that have not been accepted
Accept	Press to confirm or accept any touchscreen setting changes
Up / Down Arrows ▲ / ▼	Arrow buttons allow adjustment of settable parameters. Use up arrow to increase and down arrow to decrease.
Brightness control	Press to select brightness levels, maximum, medium high, medium and low.
Manual Inflation	3 second maximum. While button is pressed, the ventilator closes the exhalation valve and delivers an operator controlled breath to the patient.
Breath Indicator LED	Lights to indicate the ventilator is delivering a breath.
External Power LED	Lights to indicate the ventilator is powered by external power
Device Alert LED	Lights to indicate a ventilator malfunction. **WARNING Use alternate ventilation source until malfunction is identified and corrected.**

Alarms	
Handle LED	Alarm Indicators flash red or yellow for violated alarms.
Alarm Silence/ Reset button	Silences audible alarm for 60 sec; resets latched alarm messages. Press repeatedly (or push and hold for 3 seconds) to clear all latched messages.
Alarm Silence LED	LED remains lit during the alarm silence period
Message Display area	Alpha numeric display, turns color during an alarm violation and shows alarm message. Multiple alarm messages display in order of priority (red is high, amber is medium and yellow is low).
Alarm Loudness (in Alarm Screen)	1 - 10 (10 is loudest)

User Adjustable alarms	Alarm Priority	Range / Description
↑P (High Pressure)	High	4 to 99 cmH_2O / 4 to 99 mbar
↓P (Low Pressure)	High	NIV Off: 3 to 98 cmH_2O / 3 to 98 mbar (limited by PEEP + 3); 2 breath delay NIV On: 1 to 98 cmH_2O / 1 to 98 mbar (limited by PEEP + 1); 3 breath delay
↑Min Vol (High Insp./ Exp. Minute Volume)	High	NIV Off: 1.1 to 50 L/min NIV On: 1.1 to 80 L/min
↓Min Vol (Low Insp./ Exp. Minute Volume)	High	NIV Off: 0.01 to 49.0 L/min NIV On: Off, 0.01 to 49.0 L/min
↑RR (High Respiratory Rate)	Med	Off, 30-100 b/min
Apnea	High	5 - 70 seconds
↑O_2	Med	Off, 24 - 100, only available when O_2 Sensor is enabled
↓O_2	Med	Off, 22- 98, only available when O_2 Sensor is enabled
↑VT_E	Med	OFF, 0.06 to 2.2 Liters
Backup Ventilation (BUV)	Med	Can be set to be activated by either the Low Minute Volume alarm or the Apnea alarm or both via the *More/ Utilities/Custom Settings*/BUV Settings. Functional in all modes

Automatic alarms	Alarm Priority	Description
Low Baseline Pressure	High	Paw < PEEP minus 2 cmH_2O/mbar for 3 sec
High Baseline Pressure	High	Paw 5 above set PEEP at onset of a time-triggered breath
Pressure Control Setting Not Reached	High	P Peak < 50% of PCV setting for 2 consecutive breaths
Check Circuit	High	Circuit may be disconnected or proximal pressure line may be pinched or blocked
No External Power	Low	Loss of External power, automatic switchover to Internal Dual Battery System
Occlusion	High	An occlusion or restriction in the circuit that interferes with exhalation
Occlusion - Sustained	High	Occlusion continues for 10 sec or 2 breath periods, whichever is shorter
Device Alert	High	Ventilator malfunction, Device Alert LED lights red

Automatic alarms	Alarm Priority	Description
Shut Down Alert	High	Silence by pressing Alarm Silence/Reset button
Motor Fault	High	Hardware detected fault in the motor drive circuit has occurred
Internal Temperature	Low	Internal temperature is > 60° C
Backup Battery Temperature	Low	Backup Battery temperature is > 60° C
Power Pac Battery Temperature	Low	Power Pac Battery temperature is > 60° C
Power Pac Battery Pack Low	Med	Less than 2 Ah of charge is left on Power Pac battery pack
Switching to Backup Battery	Med	Indicates that the Power Pac battery pack is not available or useable. Ventilator is switching battery operation to Backup Battery.
Running on Backup Battery	Med	The Ventilator is operating on Backup Battery for > 15 minutes. Audible alarm will sound every 5 minutes thereafter
Backup Battery Low	High	Backup Battery has insufficient charge, less than 1Ah
Backup Battery Shutdown Imminent	High	Backup Battery is extremely low and will lose power very soon. Connect to external power or insert new Power Pac battery pack
Backup Battery Failure	High	Indicates a failure in Backup Battery due to communication failure with host processor or capacity is below 1 Ah
Flow Sensor disconnect	Med	Flow sensor is no longer detected or is faulty

Hardware Requirements	
Description	
Patient outlet	22 mm OD
AC Power input	100 to 240 VAC
DC Power input	12 to 24 VDC
Power switch	momentary switch to power on and off
RS-232C Interface	9 pin standard RS232 connector
Nurse Call / Remote Alarm	RJ435 connector
USB Ports	Two USB ports for connecting to central monitoring systems, uploading software upgrades or download data files.
Electrical	Applied parts type BF Class I Protection Against Electric Shock 100-240 VAC, max. 2 A, 50 / 60 Hz 12-24 VDC, max. 5 A
Internal Dual Battery System	Power Pac Battery Pack: 14.4 VDC, 6.5 amp hours Recharge: minimum 3 hours for 100% charge When new and fully charged, the primary Lithium Ion battery pack supplies power for up to 10 hours of operation at these settings: A/CMV mode, RR=15, Tidal Volume=500 mL, i time=1.0 sec, PEEP=Ø, max. airway pressure 30 cmH_2O /mbar, Power Save On, Bias flow Off. **NOTE:** The Power Pac and Backup batteries are charged whenever the HT70 is connected to an external power source. Battery charge level is best maintained by keeping the HT70 continuously connected to external power. Backup Battery: 14.4 VDC, 2 amp hour The secondary Lithium Ion backup battery will supply power for a minimum of 30 minutes.
Pneumatics	Dual micro-piston system requires no external air compressor.

Hardware Requirements	Description
Emergency Intake	Maximum inspiratory and expiratory pressure drop at single fault conditions: 10 cmH_2O/ L/sec (measured at patient connection port)
Maximum Limited Pressure (Pressure Relief)	100 cmH_2O/mbar
Environment	
Description	
Operating Temperature	–18ºC to 40ºC **NOTE:** For proper operation at low range temperatures (-18°C), the HT70 must be started in a normal room temperature environment and allowed to run for 30 minutes prior to transfer to colder environment.
Water Ingress Protection	IEC 60529 IPX4
Operating Humidity	15 to 95% non-condensing
Operating Altitude	Sea level to 15,000 ft (0 to 4,572 m) There is no altitude limitation when HT70 is operated in a pressurized environment.
Operating Pressure	600 to 1,100 mbar
Storage and Shipping Temperature	–40° C to 65° C
Storage and Shipping Humidity	0 to 95% non-condensing
Size and Weight	
Height (includes handle)	10.25 inches (26.04 cm)
Width	9.75 inches (24.77 cm)
Depth	11 inches (27.94 cm)
Weight	15.4 lbs. (6.9 kg)

Factory Default Parameters	
Patient Settings:	
MODE	A/CMV
VT (Volume Control)	500 mL
i time	1.0 sec
RR	12 b/min
Ptrig	2 cmH_2O
↓Paw Alarm	5 cmH_2O
↑Paw Alarm	40 cmH_2O
↑MV Alarm	9 L/min
↓MV Alarm	3 L/min
↑O_2	Off
↓O_2	Off
PEEP/CPAP	Off
PS	Off
Alarm Loudness Level	6

Miscellaneous	
Patient Circuit	Reusable or disposable 22 mm I.D. adult or 15 mm I.D. pediatric circuit with 3/16 inch (4.8 mm) I.D. proximal pressure sensing line, 1/8 inch (3.2 mm) I.D. exhalation valve control drive tubing, and exhalation valve. **NOTE:** Newport Medical cannot guarantee the safe use of breathing circuits that are not recommended by Newport.

(Optional) Air / Oxygen Entrainment Mixer (MX70A) Specifications

Pneumatic Requirements:	
Oxygen	35 to 65 psig (2.4 to 4.5 Bar) full operating range, maximum accuracy 40 to 50 psig (2.7 to 3.4 Bar) accuracy ± .08
Air	Atmospheric pressure
FiO2 Control	adjusted continuously from 0.21 to 1.00

NOTE: Oxygen source gas must be medical grade, 100% oxygen.

(Optional) Low Flow Oxygen Reservoir (RSV3215A)

Pneumatic Requirements:	
Oxygen	0-10 L/min
Air	Atmospheric pressure
FiO_2 Control	FiO_2, indirectly adjusted from 0.21 up to 1.00 via oxygen flow (L/min)

WARNING Appropriate oxygen monitoring is required for patient safety.

Regulatory and Agency Standards
Testing and evaluation of the HT70 Ventilator has been conducted in compliance with the following voluntary standards:
ASTM F 1246-91:2005 Standard Specifications for Electrically Powered Home Care Ventilators – Part 1: Positive-Pressure Ventilators and Ventilator Circuits
IEC 60068-2-6:2008 Environmental Testing- Part 2: Tests- Test FE: Vibration (Sinusoidal)
IEC 60068-2-27:2008 Environmental Testing- Part 2: Tests- Test EA and Guidance: Shock
IEC 68-2-34:1973 Environmental Testing- Part 2: Tests- Test Fd: Random Vibration Wide Band – General Requirements
IEC 60601-1:1988 (+A1:1991 +A2:1995) Medical Electrical Equipment – Part 1: General Requirements for Safety
IEC 60601-1-1:2000 Medical Electrical Equipment, Collateral Standard: Safety Requirements for Medical Electrical Systems
IEC 60601-1-2:2001 Medical Electrical Equipment, Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
IEC 60601-1-4:2000 Medical Electrical Equipment, Collateral Standard: Programmable Electrical Medical Systems
EC 60601-1-6:2004 Medical Electrical Equipment, Collateral Standard: Usability
IEC 60601-1-8:2006 Medical Electrical Equipment, Collateral Standard: General Requirements, Tests, and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
MIL-STD-810E Test Method Standard for Environmental Engineering Considerations and Laboratory Tests

Section 3:

Theory of Operation

Section 3:

Theory of Operation

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Device Description

The Newport HT70 ventilator is a state of the art ventilator that combines ruggedness, exceptional portability and ease of use with clinical proficiency to provide ventilatory support for infant, pediatric and adult patients. The HT70 is built for hard work with a durable polymer exterior and robust overall design that stands up to the harsh environments found in the world of emergency response, transport and homecare ventilation.

The unique design of the HT70 provides maximum mobility and safety for short or long distance transport of critically ill patients and for patients to enjoy their normal activities of daily life. This exceptional mobility is derived from two sources: the patented, power conserving dual-micro-piston technology which eliminates the need for an external compressed gas source, and the Integrated Battery System which allows virtually continuous use from battery power through hot-swappable technology.

The Integrated Battery System consists of two independent but coordinated Lithium ion batteries – the Power Pac battery, located on the back of the ventilator, and, the Backup Battery, located inside the HT70. When new and fully charged, the Integrated Battery System can provide up to 10 hours of operation at standard settings.

The Backup Battery maintains operation without interruption when the Power Pac is swapped out and also provides a minimum of 30 minutes operation when all other power sources are depleted.

The HT70 may be operated from the following power sources: A.C. (100-240 VAC @ 50 / 60), D.C. (12-24 VDC) external power source, HT70 Integrated Battery System, or the optional D.C. Auto Lighter Power Adapter accessory which enables connection to an automobile-type D.C. outlet.

All controls are easily found on the front touch screen and panel. There are no complicated menus or difficult sequences to follow in order to make necessary adjustments for common operations.

The compact lightweight HT70 ventilator incorporates powerful clinical capability for both invasive and non-invasive applications. The dual micro-piston ability to deliver variable flow enables the HT70 to provide a full range of operating modes and breath types with servo-controlled, leak-compensated PEEP.

The HT70 provides monitoring of inspiratory tidal volume (every breath), inspiratory minute volume, total respiratory rate, peak pressure, mean pressure and baseline (PEEP) pressure.

A comprehensive alarm system is built-in to alert the user to violations of user-set or ventilator set safety limits. An optional built-in oxygen monitor with high and low FiO_2 alarms may be added.

Gas delivery to the patient may be enriched with oxygen (.21-1.00) using either the optional Low Flow Oxygen Reservoir or high pressure entrainment mixer.

The HT70 has been tested for and meets the requirements for use in a medical evacuation helicopter and fixed wing transport.

Functional Subsystems Overview

Pneumatics System

The Newport HT70 pneumatics system consists of three subsystems: gas delivery, exhalation control, and safety. The gas delivery subsystem drives the movement of air into the lungs of the patient by converting electrical energy into positive air pressure. The exhalation control subsystem changes the breathing cycle from inspiration to expiration and provides positive end expiratory pressure (PEEP). The safety subsystem protects the patient by preventing high pressure and providing a capability to breathe in ambient air in the case of a potential failure of the ventilator. In addition, the safety subsystem is used to measure the air pressure requirements for ventilator safety, control, and monitoring. Refer to the section 8:
Diagram 8.1 – Pneumatics System Diagram.

Gas Delivery Subsystem

The gas delivery subsystem draws in air through the cover and inlet filter on the right-hand side of the ventilator. The semi-transparent cover allows the user to directly view the condition of the filter cover to allow for periodic replacement of the inlet filter. The air continues into the muffler, to reach the inlet side of the pump.

The HT70 does not require a gas source unless oxygen (O_2) enrichment is desired. For oxygen enrichment, an optional oxygen

mixer or low flow oxygen adapter kit may be used. Both items connect to the air intake filter cover and allow the manual adjustment of oxygen enrichment from 21% to 100%. The low flow oxygen adapter provides a low flow of oxygen up to 10 L/min.

Exhalation Valve Control Subsystem

The exhalation valve control subsystem connects within the manifold at the outlet port of the air delivery section. During inspiration, the expiratory valve control circuit actuates the exhalation control On/Off valve to pressurize the exhalation valve drive line. When Positive End-Expiratory Pressure (PEEP) is required, the exhalation control proportional solenoid valve applies pressure to the exhalation valve diaphragm, provides resistance to the expiratory flow, and maintains the patient airway pressure at a set level.

Pneumatics Safety Subsystem

The mechanical relief valve provides the primary high pressure relief function which opens at a pressure of 100 cmH_2O. The safety valve provides secondary high pressure relief function by actuating whenever the pressure exceeds 120 cmH_2O. In the event of a pump failure, the safety system allows the patient to draw ambient air into the breathing circuit through the emergency intake valve and exhale through the exhalation valve. If an occlusion blocks the circuit for greater than 10 seconds, the safety valve opens and relieves pressure in the patient circuit.

Electronics System

The microprocessor-based design incorporates a Graphical User Interface (GUI), a Single Board Computer (SBC), and the electronics to control the motor/pump, power management, and safety functions of the HT70.

Refer to section 8: Diagram 8.2 – Electronics System Diagram.

Graphical User Interface (GUI) Subsystem

The Graphical User Interface (GUI) consists of a Touch Screen LCD display, membrane panels with embedded discrete Light Emitting Diodes (LED), Display Board, Single Board Computer (SBC) and Main Control Board, and supporting electronics. Refer to the Figure 3-1. Graphical User Interface Subsystem.

The touch screen overlays the LCD display and the modes and functions are shown on the LCD display. The user can select or change these parameters by pressing the soft keys shown on the LCD display.

The HT70 powers up into a standby condition, in which, there is no patient ventilation occurring. Upon completion of programming the patient settings while in the standby mode, the user can begin patient ventilation by pressing the 'Start Ventilation' soft key displayed on the LCD.

The membrane keys and the LEDs are controlled by the microcontroller on the SBC board.

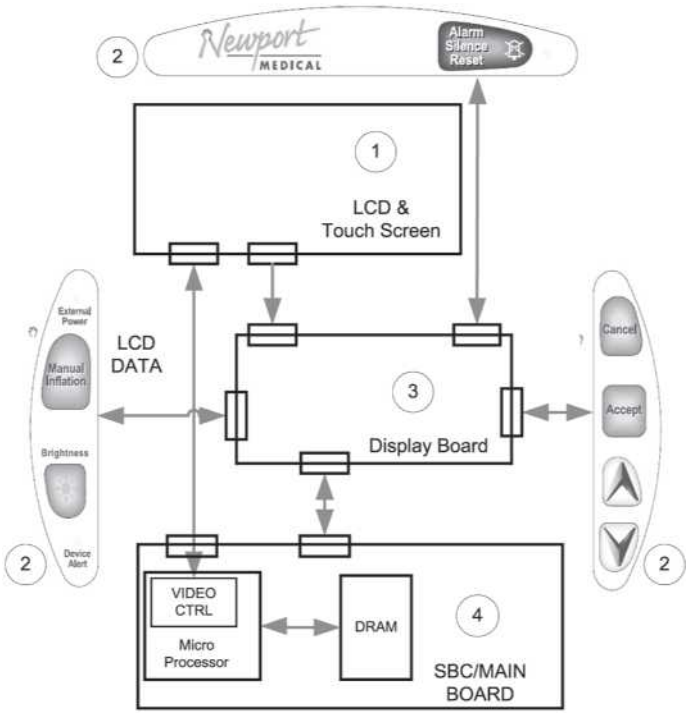

Figure 3-1 – Graphical User Interface Subsystem

Servo-controlled Motor and Pump Subsystem

The servo-controlled motor and pump subsystem utilizes the software algorithm to execute the servo controls for patient ventilation based on the patient settings. The software establishes the flow by controlling the motor speed which drives the piston-based pump. Refer to Figure 3-2. Motor and Pump Electronics Diagram.

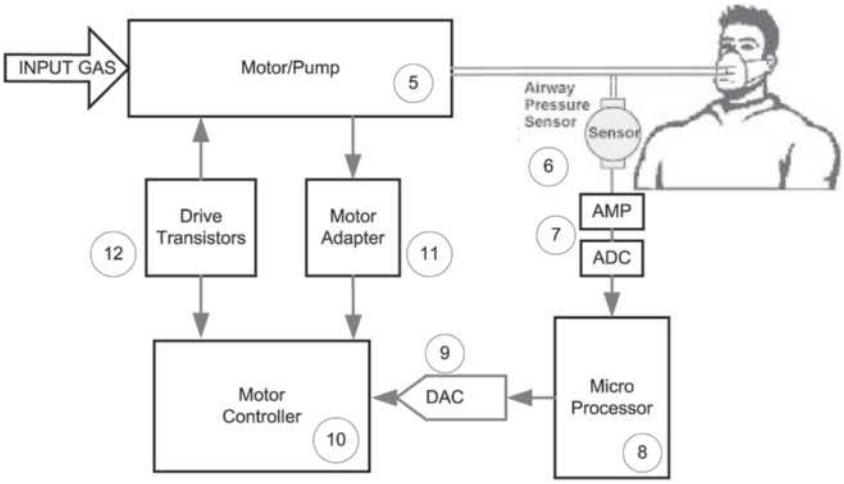

Figure 3-2 – Motor and Pump Electronics

Electronics Safety Subsystem

The HT70 can be brought to a safe state by the SBC microprocessor or independently by discrete hardware. The alarm system is comprised of two separate alarms for clinical alerts and hardware faults. The clinical alarm uses dual speakers and is controlled by the SBC microprocessor. The hardware fault alarm uses a piezo buzzer to indicate a 'Device Alert' alarm to force the system into a safe state.

The remote alarm circuit is implemented with a software configurable set/reset relay which configures the nurse call for either a normally open or normally closed system. The relay is energized to the no alarm condition and de-energized to the alarm condition to ensure that nurse call is activated on loss of power.

Upon alarm activation, the software monitors the status of the signal to ensure the speaker is active. The device alert alarm uses a high reliability piezo buzzer powered by a super capacitor to provide an alarm for a minimum of two minutes at the detection of power loss. In addition to the audible alarms, the HT70 has dual LED indicators on the handle to visually display the alarms. When a high priority alarm is active, both LED indicators flash red. When a medium priority alarm is active, the red and yellow LED indicators both flash. When a low priority alarm is active, the LED indicators flash yellow.

To prevent the accidental shut down of the HT70, the safety subsystem uses an intelligent On/Off momentary contact switch. Upon confirmation from the user by pressing the 'Accept' membrane button, software shuts down the system and triggers an alarm. Press

the 'Alarm Silence' membrane button to silence the alarm. Refer to Figure 3-3. Electronics Safety Subsystem.

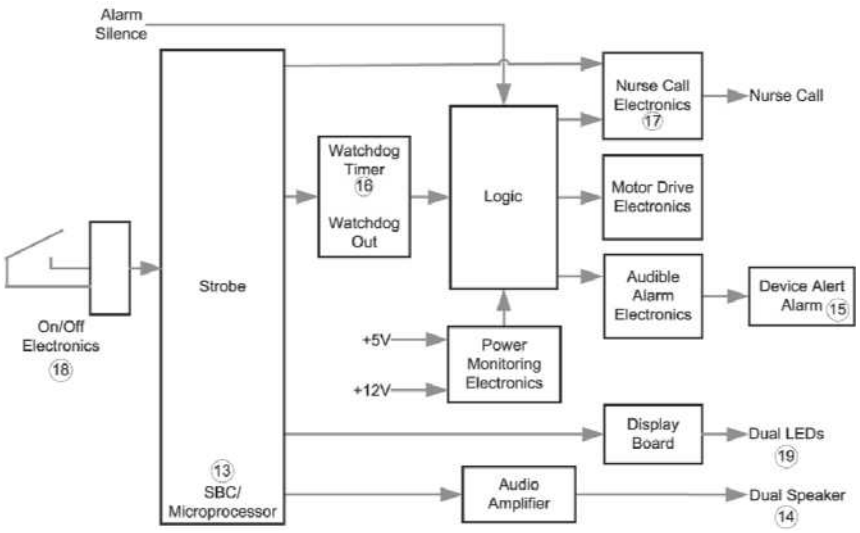

Figure 3-3 – Electronics Safety Subsystem

Power Management Subsystem

The HT70 draws power from three sources: external AC or DC power, Power Pac, and Backup Battery. External power to the HT70 is supplied through the Power Pac, The Power Pac electronics arbitrates the power source and sends the data to the Main Control board. The established power precedence is external power, Power Pac, and backup battery.

The Power Pac battery assembly slides and latches onto the HT70 and allows for easy removal when swapping the Power Pac is required. When swapping the Power Pac, the HT70 is powered from the Backup Battery.

The HT70 Backup Battery is mounted internally and cannot be swapped by the user. The Backup Battery contains the battery gas gauge and battery cells. The battery charge electronics is located on the Main Control Board. Refer to Figure 3-4. Power Management Subsystem.

The HT70 Internal Dual Battery System is charged when connected to an external AC or DC power source even while the ventilator is in use.

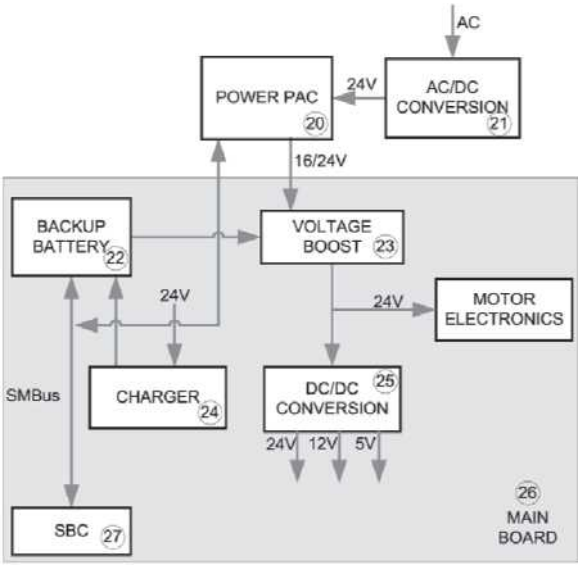

Figure 3-4 – Power Management Subsystem

Ventilation Functions Overview

Modes of Ventilation

A/CMV Mode
(Assist/Control Mandatory Ventilation)

In A/CMV mode, time activated (mandatory) breaths are delivered in accordance with the RR setting. Patients can trigger mandatory breaths in addition to, or in place of, time activated (mandatory) breaths if the effort they generate causes airway pressure to meet the Ptrig or Flow trigger setting. Every such patient effort results in a mandatory breath. The breath can be volume or pressure controlled. PEEP/CPAP may be added. In Pressure Control, tidal volume is determined by the target pressure, i-Time, and patient respiratory mechanics and in Volume Control, by the tidal volume setting.

SIMV Mode
(Synchronized Intermittent Mandatory Ventilation)

In SIMV mode, patients receive a fixed number of volume or pressure controlled mandatory breaths (time or patient activated) and may breathe spontaneously between mandatory breaths, with or without pressure support (Psupport). PEEP/CPAP may be added.

The first patient triggered breath in any mandatory breath interval will be a patient triggered mandatory breath. The patient has the rest of the interval to breathe spontaneously. If the patient does not trigger

the ventilator, and one complete mandatory breath interval has elapsed, a time triggered mandatory breath is delivered.

A mandatory breath lockout interval is activated whenever the patient triggers a mandatory breath. This limits the number of mandatory breaths (time triggered or patient triggered) the patient receives in 60 seconds to the RR (b/min) setting.

SPONT Mode
(Spontaneous Ventilation)

In SPONT mode, mandatory breaths are not delivered but the user can adjust both PEEP/CPAP and pressure support (Psupport) levels. The patient has control over each breath.

When PEEP/CPAP is set above 0, the ventilator mode is CPAP (without Psupport) or Bi-level Positive Airway Pressure (with Psupport). Ensure that Ptrig is set so the HT70 detects all spontaneous patient efforts.

Entries for tidal volume, respiratory rate, i time and Low Paw alarm limit are all inactive in SPONT mode. However, users can preset these parameters for future A/CMV or SIMV operation. As with all HT70 operating modes, Backup Ventilation is activated if the BUV linked alarm is violated.

NIV
(Non Invasive Ventilation)

The HT70 can be used for noninvasive ventilation in all modes. Press the *NIV* button on the left side of the touch screen to toggle ON noninvasive.

When NIV is on the following features are activated to assist with noninvasive ventilation:

- When PEEP is in use, bias flow becomes adjustable from 3 to 30 L/min to help manage leaks / minimize auto-triggering.
- The Low Minute Volume alarm can be turned off in the *Alarms* screen
- The Low Pressure alarm can be set closer to the base pressure (within 1 cmH_2O /mbar above baseline)

BUV
Backup Ventilation

Backup Ventilation activates when the currently linked alarm occurs. This function can be linked with the Low Minute Volume (MVl) alarm, the Apnea alarm, or both alarms. During Backup Ventilation the linked alarm(s) will sound and the message window will indicate that Backup Ventilation is in use. There are default Backup Ventilation parameters, but the user may adjust these in the *Advanced Screen*.

Backup Ventilation is functional in all modes.

Backup Ventilation is not active for 60 seconds after the user adjusts ventilator controls, changes modes or starts ventilation from the Setting condition.

During Backup Ventilation, the Alarm Silence/Reset button can be pressed to silence the audible alarm. This will not cancel Backup Ventilation.

When linked with the Low Minute Volume alarm, Backup Ventilation is based on the exhaled or delivered inspiratory minute volume, depending on whether or not the on-airway flow sensor is in use. The inspiratory minute volume may be different from the expiratory minute volume in some conditions, such as in the case of a patient breathing circuit or airway leak.

Backup Ventilation in A/CMV and SIMV Modes:

The factory default setting for Backup Ventilation in these two modes will increase the respiratory rate by 1.5 times the set rate, up to a maximum of 99 b/min. The minimum breath rate delivered is 15 b/min.

The respiratory rate (RR) will only increase up to a rate that produces a 1:1 I:E ratio even if the calculated Backup Ventilation rate is higher.

Backup Ventilation in Spont Mode:

The factory default setting for Backup Ventilation in the SPONT mode will implement these changes:

SPONT = SIMV mode

Rate = 15 b/min

Pressure Control breath type = 15 cmH_2O above set PEEP

i-time = 1.0 sec

Cancellation of Backup Ventilation

User Cancelled

If during Backup Ventilation, the user adjusts any ventilation parameter, Backup Ventilation is suspended for one minute and all user selected ventilation parameters are employed.

Sixty (60) seconds must pass after parameter adjustments before a linked alarm violation will result in Backup Ventilation.

Patient Cancelled

If linked to low minute volume, when minute volume exceeds the Low MV alarm setting by 10%, Backup Ventilation is cancelled. If linked to Apnea Alarm, after 2 minutes of Backup Ventilation it is cancelled. At that time the audible alarm stops, the alarm indicator latches and the HT70 resumes ventilation at the user-selected parameters.

Breath Types

PC
(Pressure Control Ventilation)

The HT70 targets and maintains patient airway pressure at the set pressure control level throughout inspiration. Breath termination occurs when (1) the set i time elapses, or (2) Paw exceeds the Pressure Control setting by 8 cmH_2O (mbar). Maximum airway pressure never exceeds the user set High P alarm setting.

The target airway pressure for pressure controlled mandatory breaths in A/CMV and SIMV is the display setting above ambient pressure, not above PEEP.

Both time and patient triggered mandatory breaths can be delivered in A/CMV and SIMV Pressure Control operation. During SIMV Pressure Control operation, patients can breathe spontaneously between mandatory breaths with or without pressure support.

When disconnecting the patient circuit during PC/PS ventilation, i.e. for suctioning, the flow may increase in order to compensate for the low pressure. After reconnecting the patient circuit, the flow will automatically readjust to meet the patient's demand.

VC
(Volume Control Ventilation)

During Volume Control ventilation, tidal volume can be set for mandatory breaths. If a volume setting is changed while the ventilator is operating, the change takes place in increments over a series of breaths.

When tidal volume is adjusted, inspiratory time remains constant and mandatory flow changes.

If an attempted tidal volume setting results in a flow rate in excess of 100 L/min or less than 6 L/min, flow adjustment ceases, the user is alerted by an audible beep, and a message appears in the Message Display Window. To allow further volume adjustment, change the inspiratory time to set the Flow to meet the need of the patient.

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Section 4:

Cleaning and Maintenance

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Cleaning and Maintenance

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Cleaning and Disinfecting

Use the information in this section in conjunction with hospital policy, physician prescription, Homecare Dealer or accessory manufacturer instructions.

Definitions
Cleaning: A process that uses a medical detergent or alcohol based cleaning solution to remove blood, tissue and other residue. Rinse thoroughly with sterile, distilled water and allow to air dry.

Disinfection: A liquid chemical process that kills microbial organisms.

Sterilization: A process that uses steam autoclave or ethylene oxide (EtO) this is designed to render a product free of viable microorganisms.

Caution: When using liquid chemical agents, closely follow the manufacturer's recommendations. Prior to use, verify that the agent is compatible with plastics.

WARNING Ethylene Oxide (EtO) is toxic. All accessories MUST be completely dry prior to packaging for ethylene oxide sterilizing. After sterilizing, they must be properly aerated to dissipate residual gas absorbed by the material. Follow the EtO manufacturer's recommendations for the specific aeration periods required.

Caution: Ethylene Oxide (EtO) may cause superficial crazing of plastic components and will accelerate the aging of rubber components.

Caution: Always inspect breathing circuits and accessories after cleaning, disinfecting or sterilizing to check for deterioration. If the any part is damaged or shows excessive wear, replace with a new part. Do not use cracked or damaged parts.

Ventilator

Wipe clean between patients and as needed while in use. The exterior of the ventilator should be wiped clean with a cloth dampened with a medical detergent, disinfectant or alcohol based cleaning solution.

Caution: Do not use agents that contain acetone, toluene, halogenated hydrocarbons, or strong alkalines on the face panel or ventilator housing.

Caution: Never autoclave or EtO sterilize the HT70 ventilator. These processes will damage the HT70, rendering it unusable.

Accessories

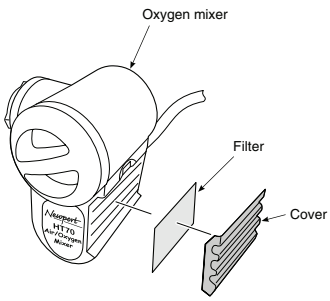
Low Flow Oxygen Reservoir
Clean and disinfect between patients and as needed while in use, refer to the instructions provided with the oxygen reservoir.

Disassembly from the HT70 ventilator: Remove the Oxygen Reservoir from the HT70 Fresh Gas Intake port. Disconnect the oxygen tubing.

General Cleaning Instructions: Hold the Low Flow Oxygen Reservoir in both hands and twist the top counterclockwise to disassemble. Separate all the parts and clean with soap and water, rinse thoroughly and then air dry.

Caution: Never mount the Low Flow Oxygen Reservoir onto the ventilator when wet.

Air/Oxygen Entrainment Mixer
Between patients and as needed while in use, the exterior of the mixer and attached hose should be wiped clean with a cloth dampened with a medical detergent, disinfectant or alcohol based cleaning solution.



Check the mixer intake filter (p/n FLT3209P) at setup and at least weekly and replace when dirty.

WARNING Always use a Mixer Intake Filter in the mixer to protect the internal mechanisms from contaminants and preserve the lifespan of your mixer.

WARNING Never reverse the Mixer Filter.

Caution: Do not wash or sterilize the Mixer Filter.

Reusable Breathing Circuits and Exhalation Valves

The HT70 ventilator may be used with a standard single limb or "J" style breathing circuit with a quality exhalation valve. Reusable breathing circuits and exhalation valves are generally provided in clean, but not sterile, condition. Follow the manufacturer's instructions to clean and/or disinfect prior to use.

WARNING Do not use electrically conductive breathing circuits. Always use clean and dry breathing circuits.

Reusable circuits should be cleaned and disinfected between patients and as needed while in use. Always use a clean, disinfected exhalation valve (and humidifier/probe assembly if appropriate) when a breathing circuit is reassembled for patient use. Clean and disinfect in accordance with the instructions provided by the manufacturer.

Caution: To avoid damage to a reusable circuit, attach and detach the circuit by grasping the cuffs at the end of the circuit tubing. Do not pull or twist the circuit tubing.

General Cleaning Instructions: Use a low flow of running water or low flow of air to clear tubings and passages of organic matter. Wash all components of the breathing circuit and exhalation valve with a soft brush in a mild medical detergent. Rinse thoroughly with sterile, distilled water. Shake off excess water and place all parts on a clean towel to air dry. (Do not heat or blow dry.) Always follow the instructions provided by the manufacturer.

Disinfect: Refer to the instructions provided by the breathing circuit and exhalation valve manufacturer.

Sterilize: Refer to the instructions provided by the breathing circuit and exhalation valve manufacturer.

Air Intake Filter (p/n HT460300)

The Air Intake Filter, located on the right side of the ventilator behind the Filter Cover, keeps dirt and particles out of the ventilator's piston system and patient gas pathway. As the filter becomes dirty it can reduce the volume of air drawn into the ventilator and add stress to the pump. Check the Intake Filter weekly. Replace with a new filter when the majority of the filter surface area is no longer white. Intake Filters are not reusable.

WARNING NEVER operate the HT70 without a clean Air Intake Filter in place. NEVER reverse the Air Intake Filter when dirty.

Proximal Inline Filter (p/n HT6004701 or equivalent)

Check the Proximal (Prox) Inline Filter weekly and replace it at least every 3 months. Discard it and replace with a new filter if it appears to have gotten wet or come in contact with a contaminant. Proximal Inline filters are not reusable. If the filter becomes occluded, replace the filter. The primary indication for this would be a Check Circuit or Prox Line Alarm.

Newport Medical strongly recommends that extra Prox Inline Filters be available at all times when using the HT70 ventilator.

WARNING Always use a Proximal Inline Filter (p/n HT6004701 or equivalent) at the Prox. Line Connector to protect the internal pressure transducers from moisture or other contaminants.

WARNING Never reverse the Proximal Inline Filter.

Caution: Do not wash or sterilize the Prox Inline Filter.

Maintenance Guidelines

Routine Maintenance

✓ Perform the Circuit Check each time a fresh circuit/exhalation valve is installed.

✓ Check the Air Intake Filter (located behind the Filter Cover) at setup and at least weekly while in use. In some environments, it may need to be checked more often. Replace when the majority of the filter surface area is no longer white. Air Intake Filters are not reusable.

WARNING NEVER reverse the Air Intake Filter when dirty.

✓ Check the Prox Inline Filter weekly. Replace with a new filter if it appears to have gotten wet or come in contact with a contaminant. Inline filters are not reusable.

✓ Check the Mixer Intake Filter (located behind the Mixer Cover) at setup and at least weekly while in use. In some environments, it may need to be checked more often. Replace when the majority of the filter surface area is no longer white. Mixer Intake Filters are not reusable.

- ✓ Inspect the AC Power Adapter on a regular basis for signs of broken or frayed cord or connectors.
- ✓ Inspect the exhalation valve after each cleaning to verify that there are no cracks or damaged surfaces.
- ✓ Wipe down the surface of the ventilator housing regularly to remove any dust that might accumulate.
- ✓ Inspect and when necessary, replace accessories.
- ✓ If service is required, contact Newport Medical or your local equipment provider..
- ✓ To preserve the Internal Dual Battery System life:
  1. Whenever possible, plug into external power source to charge the batteries.
  2. Use the optional DC Auto Lighter Cable accessory to power the HT70 when traveling by automobile or to connect to an external battery.

See Section 7 of the Operations Manual, Battery Operation for more information on the proper operation of the HT70 Internal Dual Battery System.

6 Month Maintenance

- ✓ Routine maintenance as described above
- ✓ Perform the Quick Check Procedure (described in Section 5 of the Operations Manual)

12 Month Maintenance

- ✓ Routine maintenance as described above
- ✓ Perform the Quick Check Procedure (described in Section 5 of the Operations Manual)

24 Month Maintenance

- ✓ Replace air intake and prox inline filter (HT46300 and HT6004701)
- ✓ Replace the primary integrated battery (Power Pac) (BAT3271A)
- ✓ Replace the secondary internal back up battery (BAT3205A)
- ✓ Replace the oxygen sensor (if installed) (SEN2103P)

- ✓ Replace the Coin Battery (BAT3207P)
- ✓ Replace the cooling fan filter (FCT3202P)
- ✓ Calibration and OVP performed by Authorized Service Provider

15,000 Hour Maintenance

- ✓ A comprehensive maintenance should be performed after 15,000 hours of operation. Refer to the HT70 Service Manual, or contact the Newport Medical Technical Service Department for detailed information on the 15,000 Hour Maintenance.

Do not attempt to open or perform any service procedures on the HT70. Only Newport Medical trained technicians are authorized to service the ventilator.

Newport Medical Technical Service Department:
Telephone: 800-255-6774 option #4 & option #2
Email: venttechsupport@covidien.com

General Warnings

Preventive maintenance work, repairs and service may only be performed by Newport Medical trained or factory-authorized personnel.

Always follow accepted hospital procedures or physician instructions for handling equipment contaminated with body fluids.

The ventilator and its accessories must be thoroughly cleaned and disinfected after each patient use. Perform all cleaning and sterilization of external parts and accessories in accordance with established hospital procedures and manufacturer's instructions.

Certain components of the ventilator, such as the exhalation valve and the front panel, consist of materials that are sensitive to some organic solvents used for cleaning and disinfection (e.g. phenols, halogen releasing compounds, oxygen releasing compounds, and strong organic acids). Exposure to such substances may cause damage that is not immediately recognizable.

The reusable exhalation valve, reusable breathing circuit and other parts that come in direct contact with the patient should be disinfected or sterilized between uses according to hospital policy.

Factory Maintenance or Repair

An authorized Newport Medical Instruments factory-trained technician must do all service or repairs performed on the HT70.

Caution: Always disconnect the external power supply prior to servicing.

Scheduled maintenance or repair services are available from the Newport Technical Service Department. To send your ventilator in for service, see Repackaging /Return Information that follows in this section.

Current pricing for scheduled maintenance and labor rates can be found in Newport Medical Instruments Annual Price List. To obtain a copy, please contact your local Newport Sales Representative or contact our Customer Service Department.

Repacking / Return Information

Use the original packing carton and material to ship the ventilator back to Newport Medical. Or you can contact Newport Medical Customer Service department to order replacement packing material.

Prior to returning your ventilator for service or repair you must obtain a returned goods authorization number (RGA) from our Technical Service Department. Refer to the HT70 Service Manual or contact Technical Service department for complete instructions.

See Contact Information page at the front of this manual for address, phone and website details.

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Section 5:

Service and Repair

Section 5:

Service and Repair

General Information

This chapter describes how to repair the HT70 ventilator including instructions on how to remove and replace the major assemblies, subassemblies, and components, if necessary. Unless otherwise instructed, reinstall the assemblies, subassemblies, and components by reversing the disassembly procedure.

Prior to servicing the HT70, be sure to do the following:

1. Disconnect from external power.
2. Disconnect oxygen (O_2), if applicable.
3. Put on ESD protective equipment and ensure the service area is an ESD safe environment.

WARNING
These instructions are intended for use only by a Newport Medical Instruments factory-trained technician. Do not perform any unauthorized modifications or repairs to the ventilator or its components.

Caution
To avoid damaging equipment, always use standard electrostatic discharge (ESD) precautions, including an ESD wrist strap, when servicing the ventilator.

Tools Required

#1 Phillips Screwdriver (short)

#1 Phillips Screwdriver

#1 Flat Screwdriver

5/64” Hex Driver

3/32” Hex Driver

3/16” Nut Driver

Large Pliers

Anti-static Wrist Strap

Anti-static Mat or Grounded Workstation

Removal and Replacement of the Rear Panel Assembly

Including associated assemblies

Rear Panel Assembly

1. Disconnect the power cord PWR3204P from the HT70.

2. Press the release latch and remove the Power Pac BAT3271A.

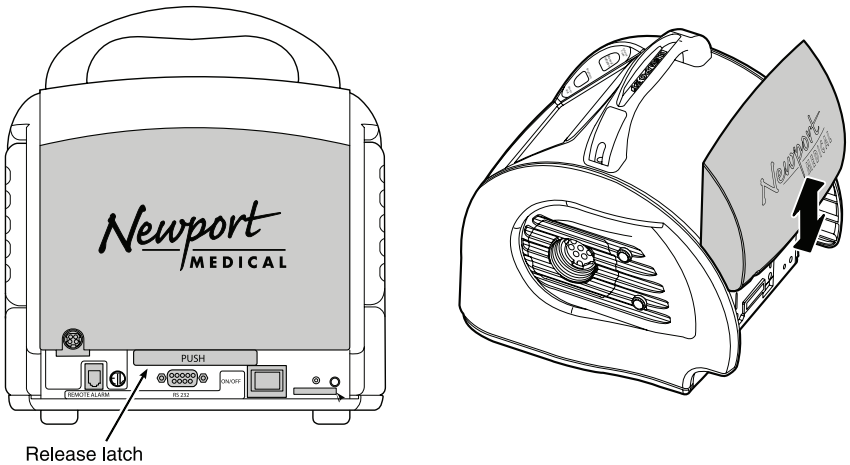

Figure 5.1 Power Pac Removal

3. Using a #1 Phillips screwdriver, remove the nine (9) outside screws on the rear panel.

   Note: The two (2) outside top screws are longer and must be used to secure the top portion only.

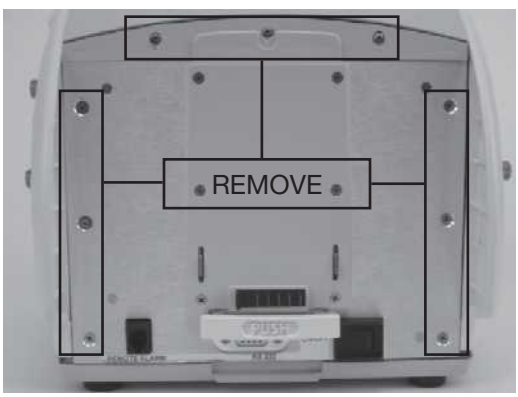

Figure 5.2 – Rear Panel Screws

4. Carefully slide the rear panel back to expose the cable harnesses and pneumatic tubes connected to the Main Control Board (MCB).

5. Disconnect the following cables from the MCB: J8, J16, J22, J26 J35 and J42.

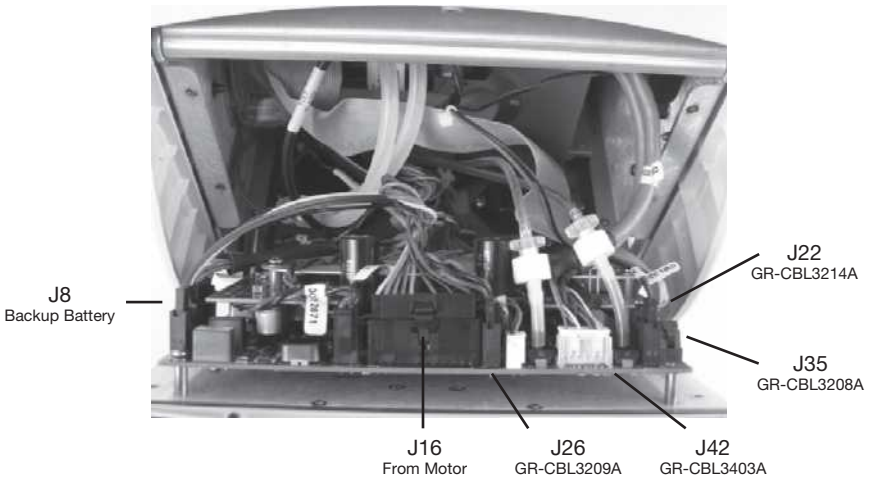

Figure 5.3 – MCB Connections

6. Unscrew the luer-lock connectors on the Yellow tube from XD2 and the small Green tube from XD22.

Figure 5.4 – Pressure Transducers

7. Disconnect the LCD data cable (GR-CBL3219A) from J800 (push tab release) on the Single Board Computer board (SBC).

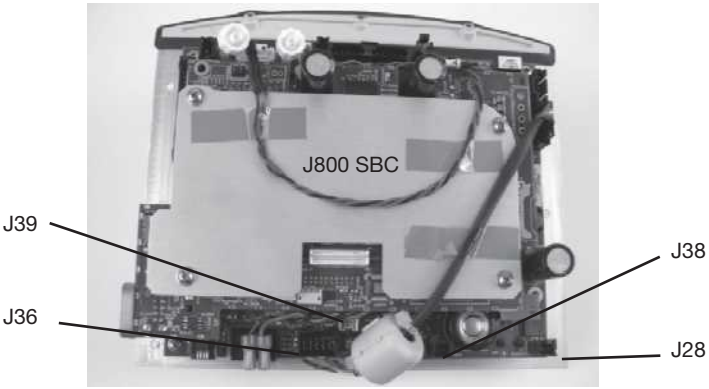

Figure 5.5 SBC and MCB Connections

8. Disconnect the remaining cables on the MCB: J28, J36, J38, and J39.

9. Lay the rear panel on the work surface.

Single Board Computer (GR-PCB3207A) Assembly

1. Using a #1 Phillips screwdriver, remove the four (4) screws (SCR3274P) and washers (WSH1512P) securing the SBC EMI shield (PLT3270M). Between the EMI shield and the SBC there are 4 spacers (SPC3205P).

   Note: The routing of the cable GR-CBL3220A (temperature sensor) is very important. If the cable is removed from the EMI . panel, ensure the cable is secured with tape NMI part number TAP077P and is properly routed when installing.

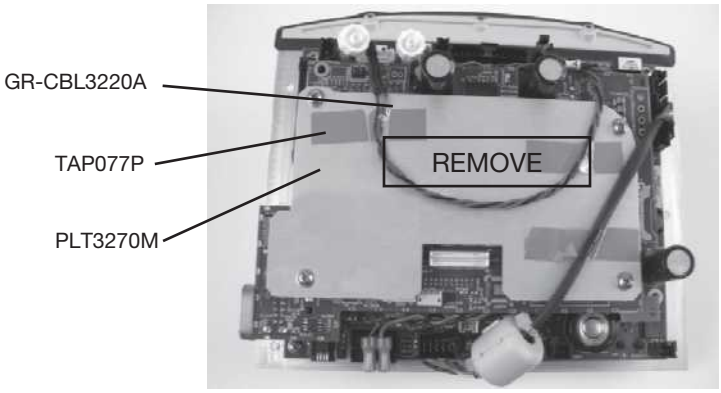

Figure 5.6 SBC EMI Shield

2. Carefully disconnect the SBC from the MCB.

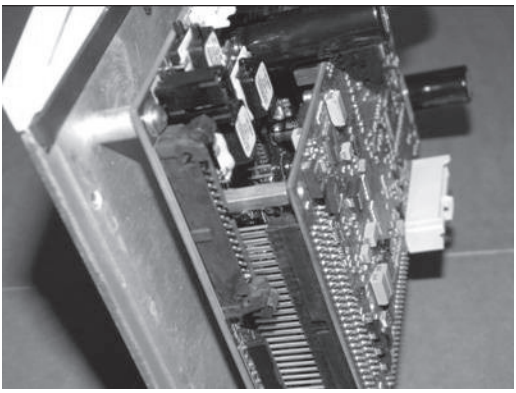

Figure 5.7 SBC and MCB Connection

3. Reverse the above steps to reinstall.

Main Control Board (MCB) Assembly (GR-PCB3252A)

1. Perform above steps for removal of Single Board Computer (SBC) assembly.

2. When ordering the SBC be sure to order GR-105795 for the Plus Units and GR-105796 for the HT70-2.

3. Disconnect the Power Pac Battery Connector Board cable (GR-PCB3203A) from J5 on the MCB.

4. Disconnect the Power Switch cable (GR-CBL3217A) from SW1 on the MCB.

Figure 5.8 Main Control Board (MCB)

5. Using a 3/16” nut driver, remove the two (2) hex jack nuts (SCR1855P) that secure the RS232 communication port.

6. Using a #1 Phillips screwdriver, remove the four (4) screws (SCR3210P) securing the MCB.

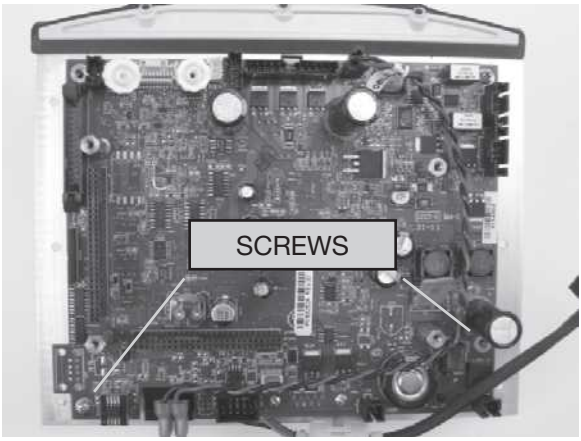

Figure 5.9 MCB Screws

7. Reverse the above steps to reinstall.

Power Switch Assembly (SWI3204P)

1. With the rear panel removed, use a small flat screwdriver to carefully press the locking tabs against the sides of the power switch.

Figure 5.10 – Power Switch

2. While pressing the locking tabs, press the back of the switch to remove the switch from the back plate.

Note: Note the position of the tabs on the switch and be sure to position the new switch in the same configuration. The black wire is

on the left side of the switch and the red wire is on the right side. The ON position faces to the right, looking from the rear of the HT70

3. Reverse the above steps to reinstall.

Removal and Replacement of the Top Case Assembly

Including associated assemblies

Inlet Air Filter (HT460300)

1. Facing the HT70, the inlet air filter is located on the right-hand side.

2. Turn the knurled screws counter-clockwise to remove.

3. Remove the inlet filter cover (CVR3215A) assembly by sliding the cover toward the back of the HT70 and lift out.

4. Remove the Air Inlet Filter Gasket (GKT3201M) by carefully pulling it away from the side of the HT70.

5. Remove the inlet air filter.

Figure 5.11 – Air Inlet Filter Cover (CVR3215A)

Figure 5.12 – Air Inlet Filter (HT460300)

Figure 5.13 – Air Inlet Filter Gasket (GKT3201M)

6. Reverse the above steps to reinstall.

Note: To reattach Air Inlet Filter Gasket (GKT3201M), use adhesive NMI part number ADH110P. Apply the adhesive to the rear surface of the gasket avoiding the slotted areas. Align the tab in the gasket with the slot on the HT70 and press firmly and allow curing overnight before returning to service.

Fan Filter and Guard (FLT3202P)

1. Facing the HT70, the fan filter is located on the left-hand side.

2. Turn the knurled screw counter-clockwise to remove.

3. Remove the fan filter cover (CVR3216A) assembly by sliding the cover toward the back of the HT70 and lift out.

Figure 5.14 – Fan Filter Cover

Figure 5.15 – Fan Filter and Guard

4. Using a #1 Phillips screwdriver, remove the four (4) screws (SCR3213P) securing the fan filter and guard (FLT3202P).

5. Discard the filter guard assembly.

6. Install the new filter assembly by reversing the above steps.

Note: The 4 screws (SCR3213P) are secured with a torque setting of 6 – 8 in-lb

Top Case Assembly (CVR3250A)

1. Refer to the Rear Panel Assembly section to remove the rear panel.

2. Lay the HT70 on the left or right side to expose the screws on the bottom plate.

3. Using a #1 Phillips screwdriver, remove the six (6) (SCR3217P) outside screws.

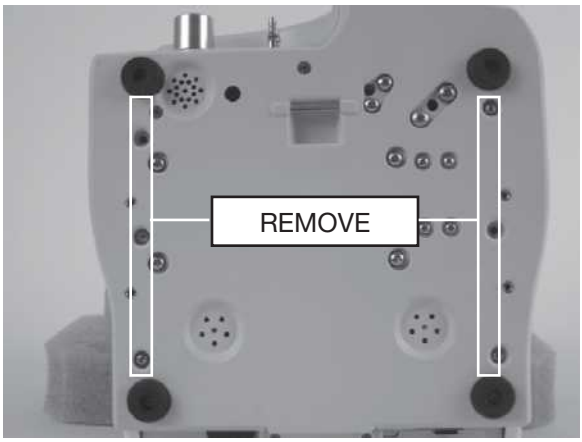

Figure 5.16 – Top Case Screws

4. Sit the HT70 upright.

5. Disconnect the inlet tube from the muffler (MUF3210A).

    a. For the HT70 with O_2 sensor, disconnect the oxygen sensor cable (GR-CBL3200A) from the sensor.

Figure 5.17 – Muffler w/Oxygen Sensor (optional)

6. Using a #1 Phillips screwdriver, remove the two (2) screws (SCR3210P) securing the muffler located on the left side when facing the rear of the HT70. Remove the muffler and gasket.

7. Carefully lift the rear portion of the top case Assembly. Ensure the fan clears the pump assembly.

8. Slide the top case assembly forward to clear the Gas Output, Proximal Line, and Exhalation Valve ports.

9. Reverse the above steps to reinstall.

   Note: When reinstalling the muffler, ensure the gasket (GKT3206M) is between the muffler and the inside of the HT70.

Fan Assembly (GR-CBL3208A)

1. Using a short #1 Phillips screwdriver, remove the four (4) screws with captured washers (SCR3218P) securing the fan and four (4) washers (WSH1512P) between the fan and housing

2. Reverse the above steps to reinstall.

Figure 5.18 – Fan Assembly

Backup Battery (BAT3205A)

1. Using a #1 Phillips screwdriver, remove the four (4) screws (SCR3215P) securing the bracket (BKT3214M) that holds the backup battery pack.

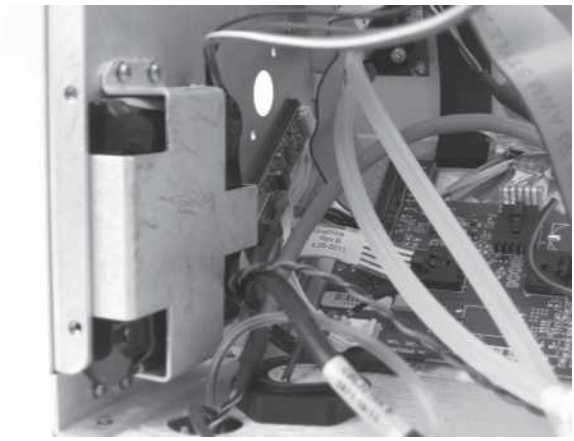

Figure 5.19 – Backup Battery

2. Remove the backup battery.

3. Install the gasket (GKT4408P) on the bottom, opposite end from the wire harness, of the battery pack.

   If the gasket on the bracket has come off, replace with a new gasket.

   Note: The gasket is double-side adhesive. DO NOT remove both protective covers. Only remove one protective cover to attach the gasket to the bottom of the battery or the middle of the bracket.

4. Reverse the above steps to reinstall.

Display Board (GR-PCB3206A)

1. Disconnect the cables from the display board at these connections: J2, J3, J4, J5, J6, J7, J8, and J9.

2. Using a #1 Phillips screwdriver, remove the four (4) screws securing the display board (3 screws (SCR3215P) and 1 screw (SCR3216P)

3. Reverse the above steps to reinstall.

   Note: During reassembly, ensure the LCD data cable GR-CBL3219A is secured by the yellow cable clamp (CLP2101P). The CLP2101P is secured with SCR3216P and is installed under the GR-PCB3206A. The ground connector for the LCD cable is installed on above the GR-PCB3206A. (Screw→Ground Connector→PCB→CLP2101P →Chassis)

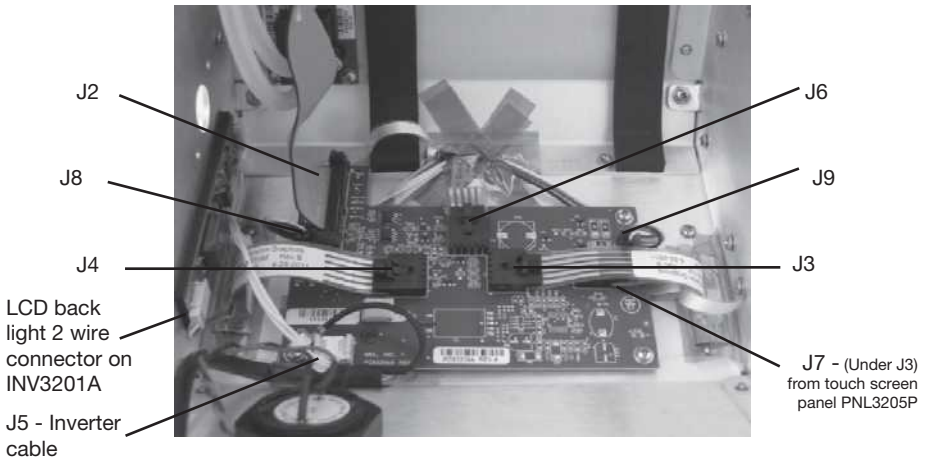

Figure 5.20 – Display Board

Chassis Assembly (GR-BSE3251A)

1. Using a #1 Phillips screwdriver, remove the two (2) screws (SCR3215P) securing the ground strips for the left and right switch membranes and use a 3/16" nut driver and remove the nut (NUT2107P) and washer (WSH3207P) securing the top membrane ground strip.

2. Using a #1 Phillips screwdriver, remove the seventeen (17) screws (SCR3215P) securing the top and sides of the chassis.

3. From the inverter board (INV3201A) remove the LCD back light cable from the 2 pin connector.

4. Carefully separate the chassis from the top case.

5. Guide the switch membrane, LCD back light, and touch screen cables through each perspective slot. Take note of each connector to ensure they are not damaged during disassembly.

6. Reverse the above steps to reinstall

   Note: When feeding the cables back through slots, ensure the EMI shielding (GKT3214M) is intact. If the gasket is not in good condition, replace the gasket. Use tape NMI part number TAP077P to cover all slots as shown in figure 5.21.

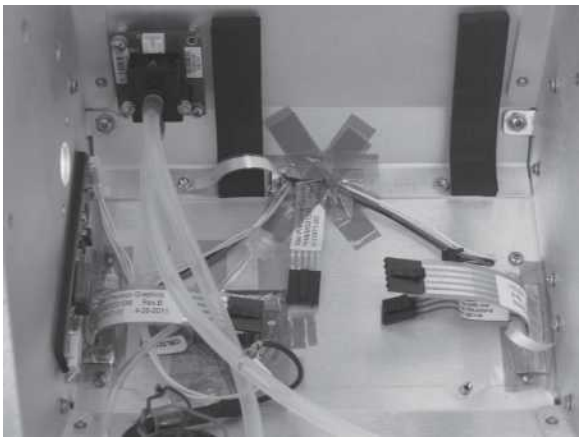

Figure 5.21

Buzzer Assembly (GR-CBL3210A)

1. Located on the front side of the chassis assembly, turn the securing mounting ring counter-clockwise to loosen and remove the buzzer cable assembly.

2. Be sure to take notice of the position of the silicon o-ring on the buzzer.

3. Reverse the above steps to reinstall.

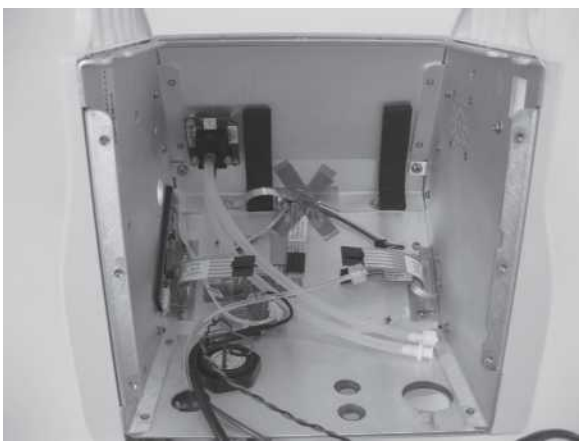

Figure 5.22 – Buzzer Assembly

LCD/Touch Screen Display (DSP3205A) Assembly

1. Disconnect the LCD Display cable (GR-CBL3219A) from the back of the display.

2. Using a #1 Phillips screwdriver, remove the four (4) screws P/N SCR2133P securing the LCD/Touch Screen assembly to the chassis.

Note: The LCD display and Touch Screen must be replaced as a whole assembly including the LCD gasket. (GKT3208M, PNL3205P and DSP2105P)

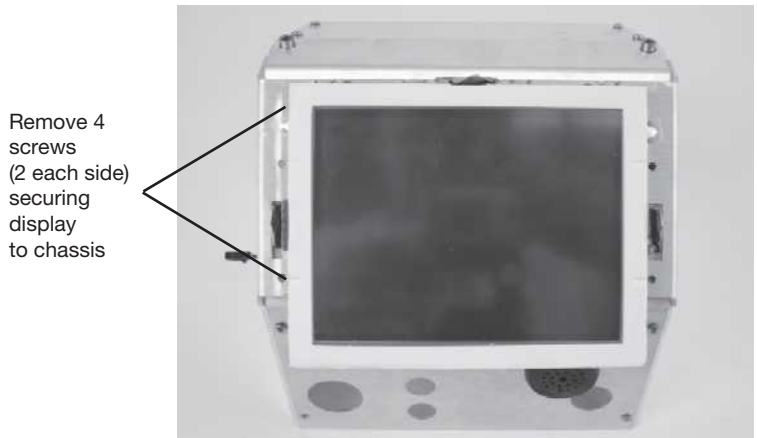

Figure 5.23 LCD Touch Screen Display

3. Reverse the above steps to reinstall.

Handle Assembly (GR-HDL3215A)

1. Using a #1 Phillips screwdriver, remove the four (4) screws (SCR3216P) securing the handle to the Top Case assembly.

2. Carefully feed the two (2) sets of LED cables through the feed holes.

3. Reverse the above steps to reinstall.

   Note: In the event an LED is no longer functioning, the complete handle assembly is replaced.

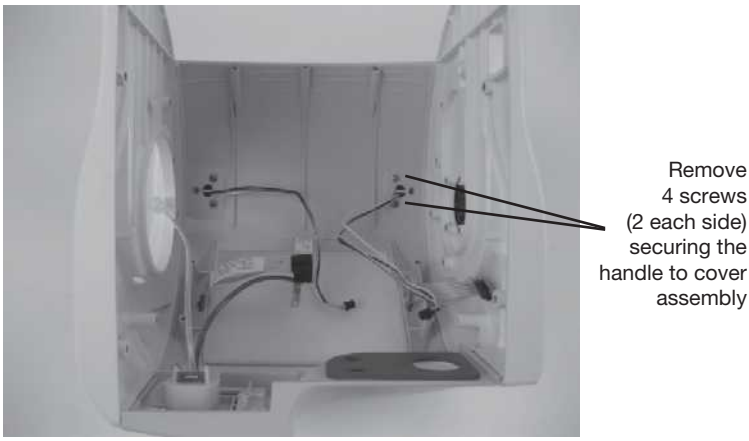

Figure 5.24 Handle Removal

Membrane Switch Assemblies

1. Using a small flat screwdriver, carefully remove the Right (MEM3210M), Top (MEM3212M), or Left (MEM3211M) Membrane Switch assemblies.

2. Feed the cable connection and ground strip through the slot openings.

3. Clean the surface area to remove any adhesive residue.

4. Remove the protective the cover from the new membrane switch.

5. After feeding the cable connection and ground strips through the slot openings, align the membrane switch on the top case and press into place.

6. Verify the membrane switch sits fully inside the recess on the top case.

   Note: After replacing any of the membrane assemblies, it will be necessary to replace the membrane overlay p/n OVR32XXA (language specific)

   OVR3215A – English
   OVR3220A – Symbols
   OVR3221A – Japanese
   OVR3222A – Spanish
   OVR3223A – Portuguese
   OVR3224A – Vietnamese
   OVR3225A – Chinese
   OVR3226A – Russian

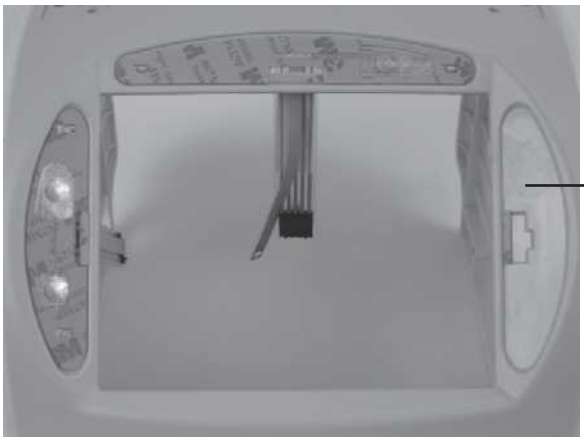

Figure 5.25 Membrane removal and replacement

Removal and Replacement of the Base Assembly

Including associated assemblies

Refer to the Rear Panel Assembly and the Top Case Assembly sections for removal of the rear panel and top case.

Speaker Assembly (GR-CBL3209A)

1. Using a #1 Phillips screw driver, remove the four (4) screws (SCR3234P) securing the speaker covers.

2. Using a #0.5 Phillips screwdriver, remove the four (4) screws (SCP2025P) securing the speakers to the bottom plate.

Figure 5.26 – Dual Speaker Assembly

3. Reverse the above steps to reinstall.

Note: Under the speakers, there is a gasket (SEL3201M). Before replacing speaker assembly, ensure the gasket is installed.

Note: Both speakers must be replaced when replacing either speaker.

Solenoid Valve Group Assembly (GR-SOL3250A)

1. Refer to Figure 5.27 and 5.28 for the following steps.

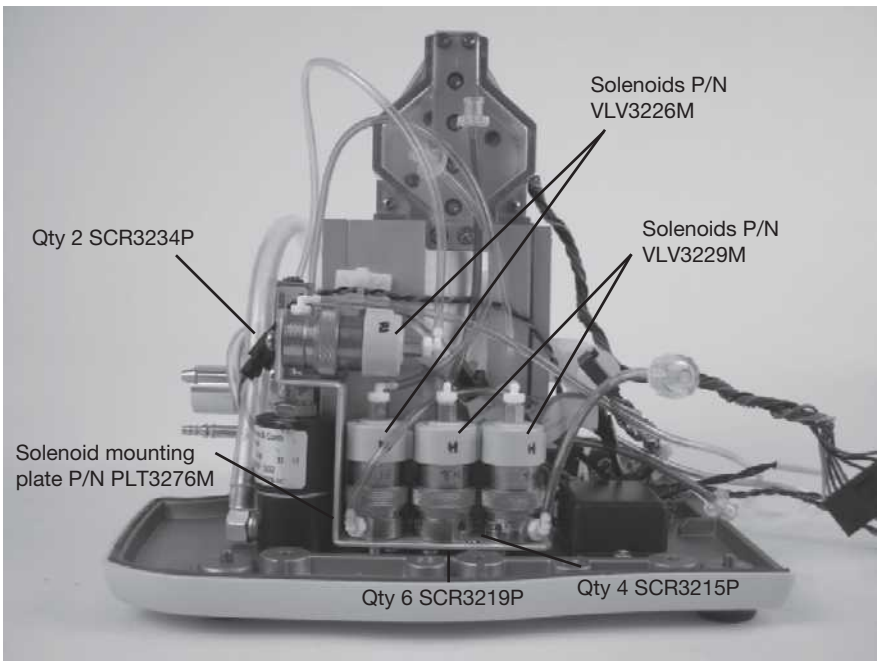

Figure 5.27 Solenoid Valve Group Assembly

Figure 5.28 – Solenoid Group Screws

2. Disconnect the Auto-zero Solenoid yellow tube from the ‘Y’ port connection on the manifold.

3. Disconnect the Auto-zero Solenoid green tube from the ‘G’ port connection on the manifold.

4. From the bottom of the base assembly, remove the 4 screws p/n SCR3215P securing the solenoid plate p/n PLT3276M to the HT70 base.

5. Remove the plate. To replace any of the four solenoids p/n VLV3226M or VLV3229M, remove the 2 screws securing the solenoid, install the new solenoid and secure with the 2 screws removed.

On / Off Valve (VLV3225M)

1. Remove the clear tube from the top of the on/off valve.

2. From the bottom of the base assembly, remove the 2 screws (SCR3219P) securing the on/off valve. Install the new on/off valve and secure with the 2 screws removed.

   Note: When reinstalling the On / Off valve, it is important to align the OUT port with the exhaust hole on the bottom of the base plate.

Safety Valve (VLV3227M)

1. Remove the clear tube from the side of the safety valve.

2. From the bottom of the base assembly, remove the 2 screws (SCR3232P) securing the safety valve. Install the new safety valve and secure with the 2 screws removed.

Note: When reinstalling the safety valve, route the cable under the pump assembly as shown in figure 5.30.

Pump Assembly (GR-PMP3230A)

1. Position the base assembly on one side to access the screws securing the pump assembly.

2. Using a Phillips screwdriver, remove the four (4) screws (SCR3219P) and two (2) screws (SCR3232P) securing the pump assembly to the base plate.

3. Reverse the above steps to reinstall.

Note: When reinstalling the pump assembly, make sure the 3 stacks of gasket GKT3212P are in place. If you need to replace the gaskets, order Qty 7.5” and cut to ½” lengths. See figure 5.30 for location.

When replacing the pump, if you have an older style (PMP3200A, PMP3216A) you will also need to order SPC3206x6 for the difference in weight.

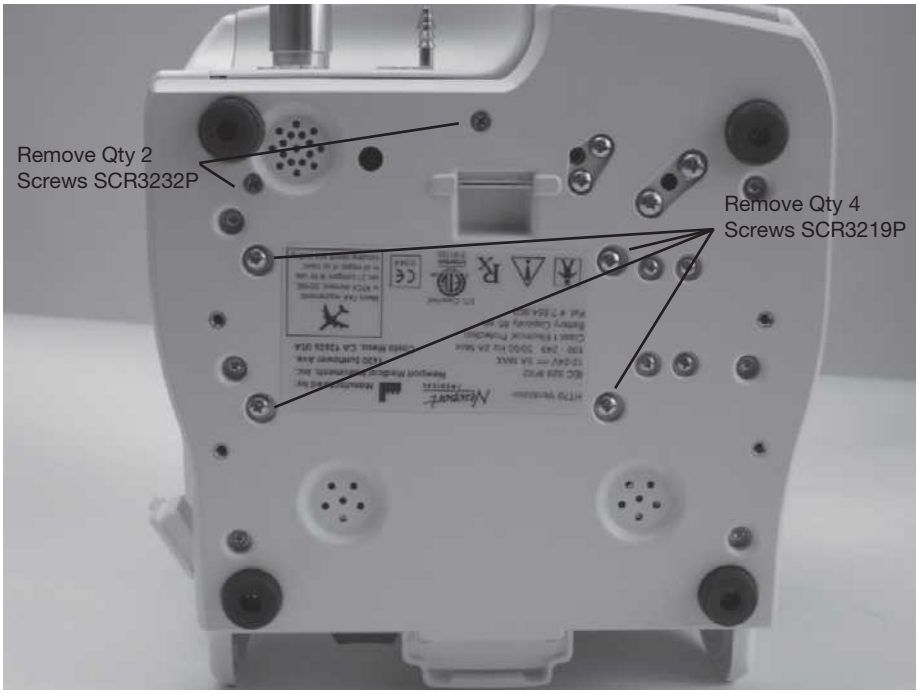

Figure 5.29 – Pump/Manifold Screws

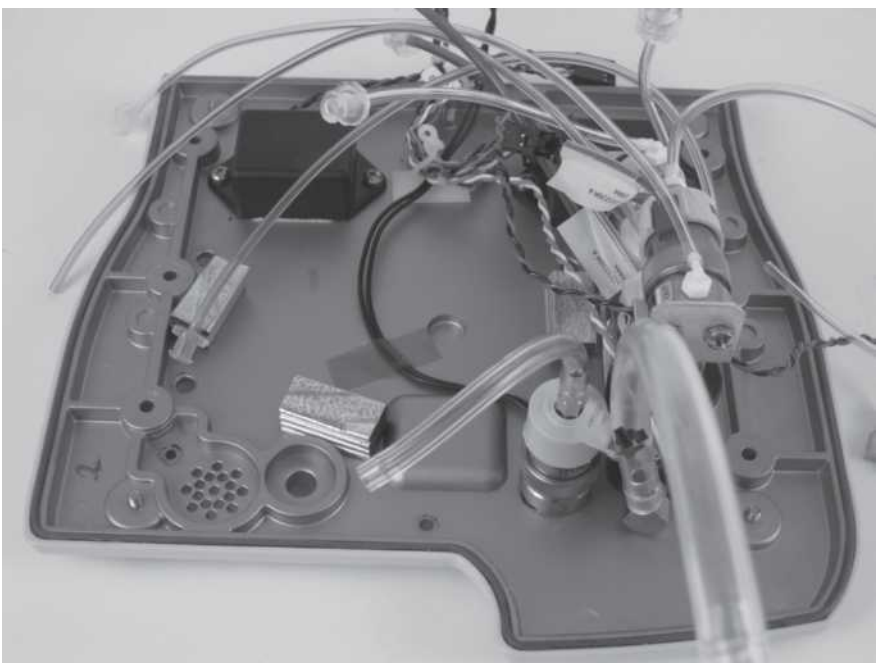

Figure 5.30 Base Plate

Manifold Assembly (MNF3200A & GR106764)

1. Refer to the Solenoid Valve Removal section for regarding the disconnection of the pneumatic tubes.

2. Refer to Figure 5.29, Pump Assembly Removal, regarding the removal of the pump assembly from the base plate.

3. Disconnect the black and red wires from the Proportional solenoid.

   Note: Note the black wire connects to the outside connection on the proportional solenoid. Make sure to reconnect the wires properly.

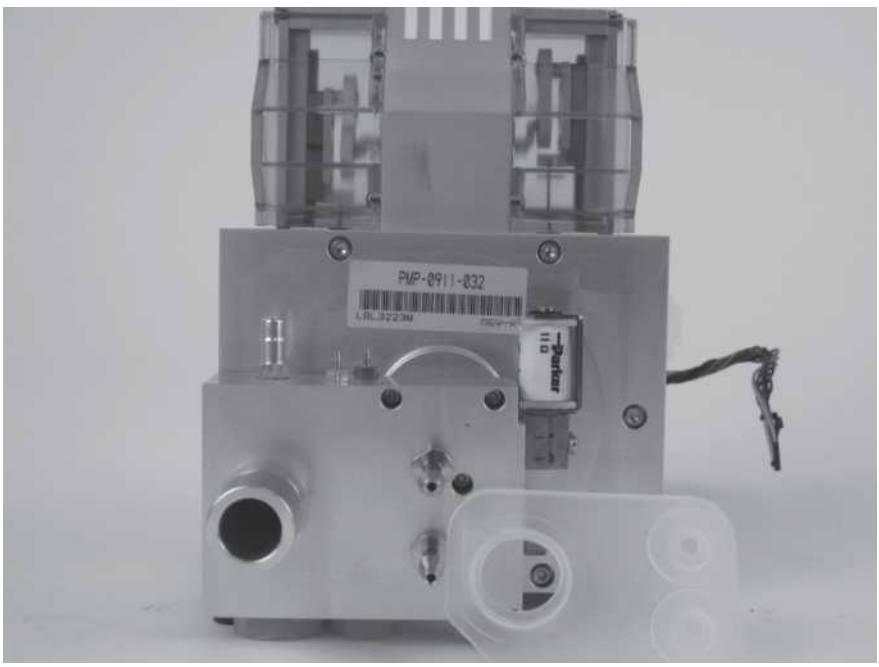

Figure 5.31 – Proportional Solenoid Wire Connections

4. Using a 3/32” hex driver, remove the three (3) screws (SCR3207P) and washers (WSH1250P) securing the manifold to the pump assembly.

5. Using a 1/16” hex driver, remove the two (2) screws (SCR3231P) and washers (WSH3207P) securing the Proportional solenoid valve (VLV3217P) to the manifold.

6. Reverse the above steps to reinstall.

Note: When reinstalling the Proportional solenoid valve to the manifold and the manifold to the pump assembly, ensure the o-rings (ORG200P) are fully seated to avoid any possible damage to the o-rings.

Note: The gasket (GKT3254M) is installed over the gas outlet and Prox and Exh fittings.

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Section 6:

Performance Verification

Section 6: Performance Verification

General Information

This chapter describes how to perform a Quick Check, calibration, and Operational Verification Procedure of the HT70 ventilator. These performance checks ensure the HT70 is in proper operating condition after a service and/or repair has been performed.

WARNING Do not use the HT70 ventilator unless it passes the OVP.

Test Equipment Required

- Certified calibration analyzer PTS2000 or equivalent
- Oxygen Analyzer
- Newport Medical disposable patient breathing circuit (BCD43811P) or equivalent
- Adult 500 mL test lung (LNG800P or LNG600A with an Rp20 parabolic airway restrictor)
- Parabolic Airway Restrictors – Rp20 & Rp50
- Medical grade oxygen source
- Cap (CAP100P) to occlude the patient circuit Y-piece or equivalent (Qty 2)
- 20 cc Locking Syringe (TOL1952P)
- T-connector (TOL200A)
- Oxygen Reservoir (RSV3215A) and Flow Meter (FLW300A)

Caution The accuracy of all test equipment (electronic or pneumatic) used for verification or calibration procedures should be certified annually by a testing laboratory before use.

Quick Check

Introduction

This procedure is intended to assist qualified operators establish a routine program for verifying proper HT70 operation. Perform the Quick Check procedure before the first patient use, between patient uses, every 6 months.

HOMECARE PROVIDERS: This procedure should be performed prior to delivery of the HT70 to a patient's home and every 6 months.

NOTE: If Power Save is On, the screen will go to sleep (go blank) when not used for two minutes. Just touch any button or the screen anywhere to bring it back into view.

WARNING Do not use the HT70 if it fails the Quick Check Procedure.

Pre-test Inspection

1. Inspect the Air Intake Filter through the filter cover on the right side of HT70. Replace the filter if it is dirty.

2. Examine the test lung and patient circuit to ensure that there are no holes that will cause leaks.

3. Verify that the A.C. power adapter PWR3204P is in good condition.

Setup and Circuit Check

1. Connect the A.C. power adapter to an A.C. power source.

2. Verify that the External Power LED is lit.

3. Turn the ventilator on and verify that the audible alarm sounds and the LEDs light during the self test.

4. Connect a breathing circuit with exhalation valve

5. Perform the Circuit Check.

   a. Connect the breathing circuit to the ventilator as it will be used for your patient.

   b. Touch the *Circuit Check* button at the top of the touch screen.

   c. For Step 1, occlude the patient connection end of the circuit. (Do not use a test lung.)

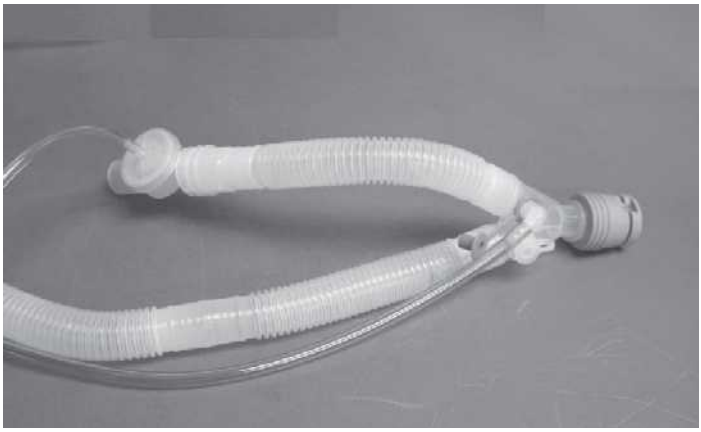


Figure 6.1

d. Press the *Accept* button to confirm and start the Circuit Check.

e. For Step 2, open the end of the patient circuit.

f. Press the *Accept* button to continue the Circuit Check.

g. If the test passes, the message “Circuit Check PASSED Press Accept to Confirm” will be displayed.

h. When the Circuit Check is completed, press the Accept button and adjust patient settings as needed and touch the *Start Ventilation* button to begin ventilation.

i. To cancel the Circuit Check and return to the Startup Screen, press the *Cancel* button.

j. If the Circuit Check fails:

   i. The message “Circuit Check FAILED Press Accept to Confirm” will be displayed.

   ii. Press the Accept button to return to Startup Screen.

   iii. Restart the Circuit Check.

   iv. Check that the accessories and all tubing connections are properly connected and leak free.

   v. Then touch the *Circuit Check* button to redo the test.

   WARNING Do not use the HT70 if the Circuit Check fails, inadequate ventilation may result. Use an alternate method of ventilation. Contact Newport Medical Technical Support.

   NOTE: The Circuit Check results are logged into Event History and retained after power down.

6. Connect the test lung to the breathing circuit.

7. Press the Brightness button and verify that it scrolls through 4 levels of brightness. Set the brightness at desired level.

8. Set the ventilator to the following Standard Test Settings as shown in Table 6.1 and press “Start Ventilation”.

STANDARD TEST SETTINGS (STS)

Parameter	Patient Setting
Advanced/ More Screen	
Flow Wave Pattern	Square
NIV	Off
Slope/Rise	5
PS Exp Thresh	25%
PS Max i-Time	3.0
Alarm Screen	
↓P (Low Airway Pressure)	3 cmH_2O / mbar
↑P (High Airway Pressure)	99 cmH_2O / mbar
↑Min Vol (High Inspiratory Minute Volume)	50 L (maximum setting)
↓Min Vol (Low Inspiratory Minute Volume)	1 L (minimum setting)
↑RR	100
Apnea	60
↑FiO_2	Off
↓FiO_2	Off
Alarm Loudness	1
Main Screen	
Mode	A/CMV
Breath Type	VC
VT	500 mL
Flow	30
i-Time	1.0 sec
RR	15 b/min
P_{trig}	1 cmH_2O / mbar
PEEP/CPAP	Off
PS	10 cmH_2O / mbar
PC	15 cmH_2O / mbar

Table 6.1 - Standard Test Settings

Quick Check Procedure

1) No External Power Alarm Check

a) Disconnect the A.C. power adapter. Verify that there is an audible alarm and the alarm LEDs in the HT70 handle turn on. Verify that the Ext. Power LED turns off, and the Message Area turns yellow and displays the No External Power alarm message. Confirm that HT70 continues to ventilate.

b) Press the Alarm Silence/Reset button and confirm that its LED lights yellow, the audible alarm turns off and the message area returns to black.

c) Press the Alarm Silence/Reset button again and confirm that the alarm message clears.

d) Reconnect the A.C. power adapter. Verify that the Ext. Power LED lights green.

2) Alarms and Indicators Check

a) High ↑P Alarm

i) Set the High Paw alarm limit to 20 cmH_2O/mbar. Verify that an audible alarm sounds, the RED LED in the handle flashes, the High Paw message displays and that inspiration ends when pressure reaches the high limit. Set the High Paw alarm limit back to 99 cmH_2O /mbar and verify that the audible alarm stops, the RED LED in the handle is cleared and the alarm message remains. Press the Alarm Silence/Reset button to clear the alarm message.

b) Low ↓P Alarm

i) Disconnect the test lung from the breathing circuit and verify that after two breaths an audible alarm sounds and the Check Circuit or Prox Line/Low Pressure alarm message displays

ii) Attach the test lung to the breathing circuit and verify that the audible alarm ceases and the alarm message remains. Press Alarm Silence/Reset button to clear the message.

3) Pressure Gauge / PEEP Check

a) Verify that the pressure gauge moves up and down with each breath.

b) Select PEEP and Peak Paw to display in each of two Monitor Data buttons.

c) Adjust PEEP to 5 cmH_2O. Verify that the Monitor Data button displays a PEEP value of 4 to 6 cmH_2O. Reduce PEEP to zero.

d) Select Pressure Control and set pressure at 20 cmH_2O. Verify that the Monitor Data button displays a Peak Paw of 17 to 23 cmH_2O.

e) Place the ventilator in Volume Control.

4) Tidal Volume/Minute Volume/Respiratory Rate Monitor Check

a) Confirm that Tidal Volume is set to 500.

b) Select VT, Min Vol and RR Tot to display in each of three Monitor Data buttons. Verify that VT= 450-550, Min Vol = 6-9 and RR Tot = 13-17.

5) Integrated Battery System Check

a) Unplug the A.C. power adapter, clear the alarm with the Alarm Silence/Reset button. Verify that HT70 continues to ventilate and the Power Pac battery gauge (blue icon) reads at least 80%. If battery charge level is not sufficient, plug into external power to fully charge the Integrated Battery System.

b) Remove the Power Pac battery pack. Verify that HT70 continues to ventilate, the alarm sounds, the alarm LEDs light and the message in the message area indicates that the Backup Battery is in use.

c) Verify that the battery gauge is now red (for internal backup battery) and reads at least 80%. If the internal backup battery charge level is not sufficient, re-insert the Power Pac battery and plug into external power to fully charge the system.

d) Replace the Power Pac battery pack and verify that the audible alarm clears but the message remains.

e) Reconnect the A.C. power adapter into the Power Pac battery pack and confirm that the Ext. Power LED turns green.

f) Press the Alarm Silence/Reset button repeatedly until all alarm messages are cleared.

HT70 Ventilator Quick Check Record

Pass / Fail Check-Off Sheet

Preparation for Use Tests	Test Results
1. No External Power Alarm Check	Pass _____ Fail _____
2. Alarm & Indicators Check	
High Paw	Pass_____ Fail _____
Low Paw	Pass _____ Fail _____
3. Pressure Gauge / PEEP Check	Pass _____ Fail _____
4. Volume / Minute Volume / Respiratory Monitor Check	Pass _____ Fail _____
5. Integrated Battery System Check	Pass _____ Fail _____

The ventilator is ready for operation when all tests have passed each test.

Note: Use the space below to document any comments or inspection of the unit, corrective actions taken, or recommendations for further action.

_____

_____

_____

_____

_____

Completed by: _____ **Date:**_____

Facility: _____

Serial #: _____

Unit Hours: _____

Table 6.2 – Quick Check Record

Calibration Procedures

Introduction

The HT70 calibration procedure should be performed for any repair, scheduled preventive maintenance (every 24 months), 15,000 hour service, or OVP failure. The calibration procedure is not required for routine maintenance except in the event of a failure

Equipment Setup

1) Plug the HT70 into AC power and leave powered off for **30 minutes** prior to testing to ensure the ventilator has sufficient power to complete the calibration testing.

Figure 6.2 – Equipment Setup

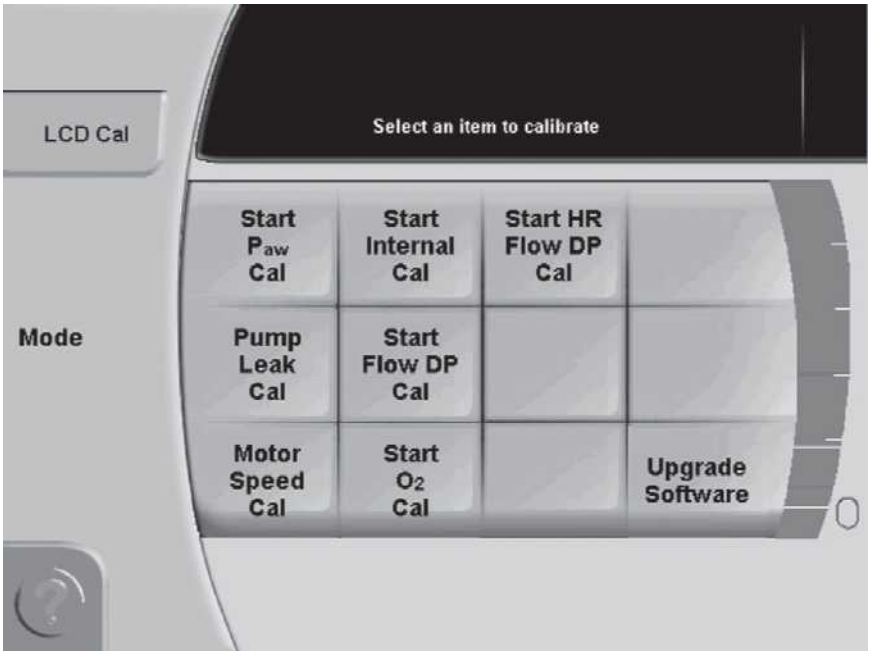
Pressure Transducer Calibration

The pressure transducer calibration is based on two reference points: (1) zero pressure (the sensor port open to atmosphere) and (2) reference pressure (an applied pressure of 60 ± 0.02 cmH_2O to the pressure transducer).

1) Remove the Power Pac and, using a #1 Phillips screwdriver, remove the screws securing the Rear Panel Assembly. Refer to section 5 for the detailed instructions.

2) Press and hold the manual inflation button and power up the ventilator to activate the Calibration Screen – Figure 6.3.

   Note: Do not release the manual inflation button until the Start Up window is displayed



3) Disconnect the luer-lock on the Yellow tubing connected to the Airway Pressure Transducer (XD2) mounted to the Main Control Board PCB.

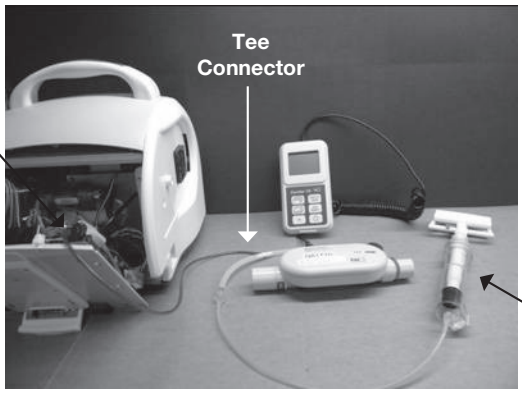
   a) Select 'Start Paw Cal' to zero the reading.

      Note: The Message 'Apply zero pressure to the Airway Pressure Transducer. Press zero when ready'

   b) Verify the sensor port is open to atmosphere and press 'Zero Ready'.

      Note: The Message 'Apply 60 cmH_2O pressure to the Airway Pressure Transducer. "Press Pressure Ready" when ready' is displayed.

4) Connect the certified test analyzer and locking pressure syringe (TOL1952P) to XD2 using a Tee connector.



Refer to Figure 6.4 – Transducer Calibration

5) Adjust the syringe and monitor the analyzer until a pressure of 60±0.02 cmH2O is achieved. When the reading is stable, press the "Pressure Ready". Avoid over-pressurization above 100 cmH2O to prevent damage to the transducers.

6) If the calibration is passed, the message "Calibration passed". Press the 'Accept Cal' button to save the cal value; Press the 'Accept Cal' button.

   a) If the test fails, press 'Cancel Cal' and repeat the calibration procedure.

      Note: Any time during the process, the calibration may be canceled by pressing "Cancel Cal".

7) Disconnect the luer-lock on the Green tubing connected to the Internal Pressure Transducer (XD22) mounted to the Main Control Board PCB.

   a) Select 'Start Internal Cal' to zero the reading.

      Note: The Message "Apply Zero Pressure" to the Internal Pressure Transducer. Press Zero When Ready"

   b) Verify the sensor port is open to atmosphere and press 'Zero Ready'.

      Note: The Message "Apply 60 cmH2O" pressure to the Internal Pressure Transducer. Press "Pressure Ready" when ready' is displayed.

8) Connect the certified test analyzer and locking pressure syringe TOL1952P) to XD22 using a Tee connector.

9) Adjust the syringe and monitor the analyzer until a pressure of 60±0.02 cmH2O is achieved. When the reading is stable, press the "Pressure Ready". Avoid over-pressurization above 100 cmH2O to prevent damage to the transducers.

10) If the calibration is passed, the message ”Calibration passed. Press the ‘Accept Cal’ button to save the cal value”. Press the ‘Accept Cal’ button.

    a) If the test fails, press ‘Cancel Cal’ and repeat the calibration procedure.

11) **Note:** Any time during the process, the calibration may be canceled by pressing “Cancel Cal”.

12) Reconnect the luer-lock to XD2 and XD22 transducer pressure tubes.

13) Power the HT70 off and Rreassemble the Rear Panel Assembly and reinstall the Power Pac removed in step 21. Renter calibration screen as performed in step 2.

Motor Speed Calibration

1) Disconnect the circuit from the output port

2) On the calibration screen, select “Motor Speed Cal”.

3) The unit will slowly increase speed motor. Wait approximately 3 minutes for the ventilator to perform and complete this calibration.

   Note: If the calibration is passed, the message ‘Calibration passed. Press the ‘Accept Cal’ button to save the cal value’.

4) Press the ‘Accept Cal’.

    a) If the test fails, press ‘Cancel Cal’ and repeat the calibration procedure.

Pump Leak Calibration

1) On the Calibration screen, select ‘Pump Leak Cal’.

   Note: The Message ”Attach the Rp50 to the patient outlet. Press the button when ready”

2) Connect an Rp50 parabolic resistor to the Main Flow Outlet and DO NOT block the open end.

3) Select ‘Rp50 Ready’.

4) The unit will slowly increase speed. Wait for the ventilator to perform and complete this calibration.

5) If the calibration is passed, the message ‘Calibration passed. Press the ‘Accept Cal’ button to save the cal value’.

    a) If the test fails, press ‘Cancel Cal’ and repeat the calibration procedure.

6) Remove RP50 from Gas Output and Reconnect breathing circuit to Gas Output.

FiO2 Sensor Calibration

1) Press the 'Start O2 Cal' button.

2) Press the 'O2 Ambient Ready' button.

   Note: During the test the ventilator will display 'Please Wait'. Upon completion, the ventilator will state 'O2 100% Ready'.

3) Connect the HT70 Low Flow Oxygen Reservoir to the ventilator.

4) Connect the O2 gas source to your flow meter. (note: make sure the flow meter adjustment knob is in the off position.)

5) Turn on the oxygen source and turn the flow meter up to 10 L/min to flush the reservoir.

6) Press the 'O2 100% Ready' button.

   Note: During the test the ventilator will display 'Please Wait'.

7) After the button is pressed you will need to adjust the flow meter in order to maintain a steady flow of O2 going through the system.

8) Once the "Calibration Passed" shows on the message screen you will need to adjust the flow meter down to zero and press Accept Cal button on the main screen.

9) Disconnect all accessories from the air inlet port

LCD Calibration

1) Press the 'LCD Cal' button.

2) Follow the instructions as indicated on the screen.

Flow Sensor Transducer Calibration
Flow Sensor Board GR-PCB3212A Calibration

Note: Flow Sensor Transducer Calibration is only required for PLUS units.

1) Select "Clear Tube DP Cal".

2) Confirm transducer is open to atmosphere and select "Zero Ready".

3) Use a precision pressure regulator to obtain a pressure of 1.0 cmH_2O.

   a) Tee a pressure gauge (PTS2000 Certifier FA Plus) to the output of the pressure regulator.

   b) Apply the pressure to the lower port of the flow sensor connector.

   c) Adjust the regulator until the output is 1.0 $cmH_2O \pm 0.05$.

   d) Select “Pressure Ready”.

4) Select “Accept Cal”, and then remove the pressure.

5) Select “Blue Tube DP Cal”.

6) Confirm transducer is open to atmosphere and select “Zero Ready”.

7) Adjust the precision pressure regulator to obtain a pressure of 2.0 cmH_2O.

   a) Apply the pressure to the upper port of the flow sensor connector.

   b) Adjust the regulator until the output is 2.0 $cmH_2O \pm 0.05$.

   c) Select “Pressure Ready”.

8) Select “Accept Cal” and then remove the pressure.

9) Upon completion, press the On/Off Switch and the ‘Accept’ button to power down the ventilator.

Operational Verification Procedure (OVP)

Note: If the HT70 has been repaired, had a scheduled PM or 15000 hour service performed, or failed during the OVP testing, perform a full system calibration prior to performing the OVP.

Electrical Safety Testing (EST)

1) The electrical safety testing is not required as the HT70 Ventilator is operated on DC power from the AC/DC power supply.

Equipment Setup

1) Plug the HT70 into AC and leave off for **30 minutes** prior to testing to ensure the ventilator has sufficient power to complete the calibration and testing.

2) Connect a patient circuit and test lung to the HT70 as shown in Figure 6.2.

Front Panel Test

1) Press the On/Off switch once. The ventilator performs a self-test. During the self-test, verify that no error messages are displayed.

2) Using the Touch Screen, select More>Utility Settings>Date/Time (For HT70Plus it is time and altitude. Altitude should be set to 0.)

   a) Using the Touch Screen, touch the year and use ▲Up/▼Down button to select the correct Year.

   b) Repeat the above step for the Month, Day, Hour, and Minute.

3) When finished, select Accept.
4) Press all membrane switch buttons and verify that all buttons are functional.

AC Power Loss and Shutdown Buzzer Alarm Test

1) Disconnect the ventilator from A.C. power. Verify the “Loss of External Power, Switching to battery power” alarm is activated.

2) Shutdown the ventilator by pressing the On/Off switch once. Touch the “Accept” button on the touch screen to confirm.

3) Verify the audible shutdown alarm activates and allow the alarm to continue for at least two (2) minutes before pressing the Alarm Silence button.

4) Connect the ventilator to A.C. power and power up the ventilator.

Circuit Check

1) If the calibration procedures were not required, perform a circuit check as outlined in the Setup and Circuit Check section on page 6-2.

LED / Solenoid Check

1) Turn on the ventilator and hold “cancel” until the Service screen comes up – Figure 6.5.

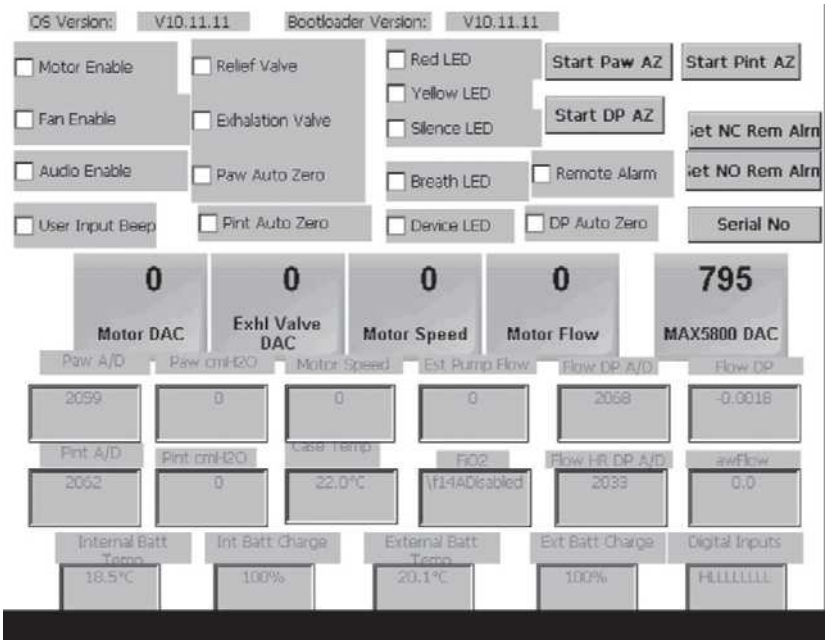


Figure 6.5 – Service Screen for the HT70 Classic

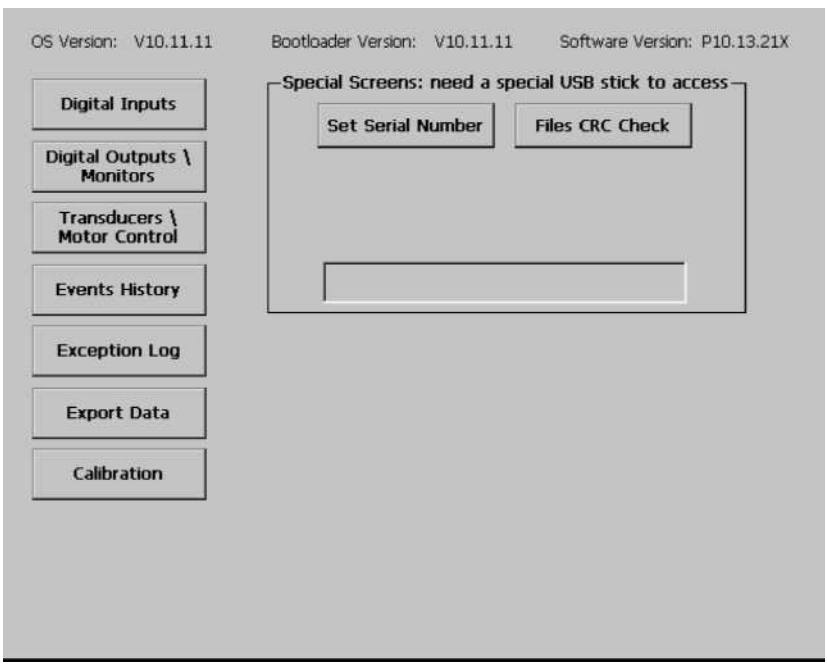


Figure 6.6 – Service Screen for HT70 Plus and HT70-2 Models

2) Then select Digital Outputs/Monitors

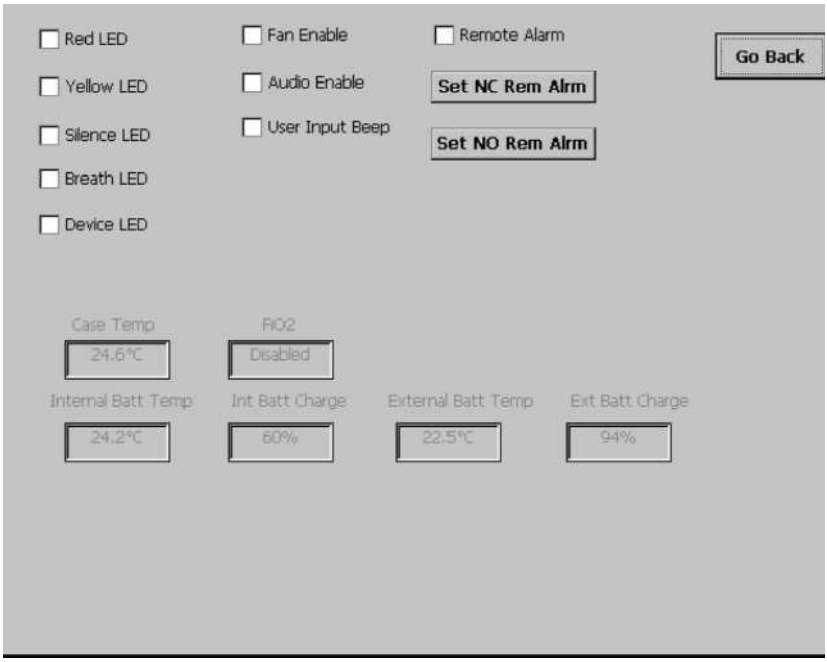


Figure 6.7 – Digital Inputs & Outputs for HT70 Plus and HT70-2

3) Then use the touch screen to activate and deactivate each item below to verify operation:

- Red and Yellow LED – The red and yellow indicators activate
- Alarm/Silence LED – The indicator activates
- Breath LED – The indicator activates
- Device Alert LED – The indicator activates
- Fan – Listen for the fan to start

4) To test the remote alarm, use your facility's remote alarm system as applicable.

5) On the screen press (Go Back) to go back to the service screen, then select Transducers/Motor Control.

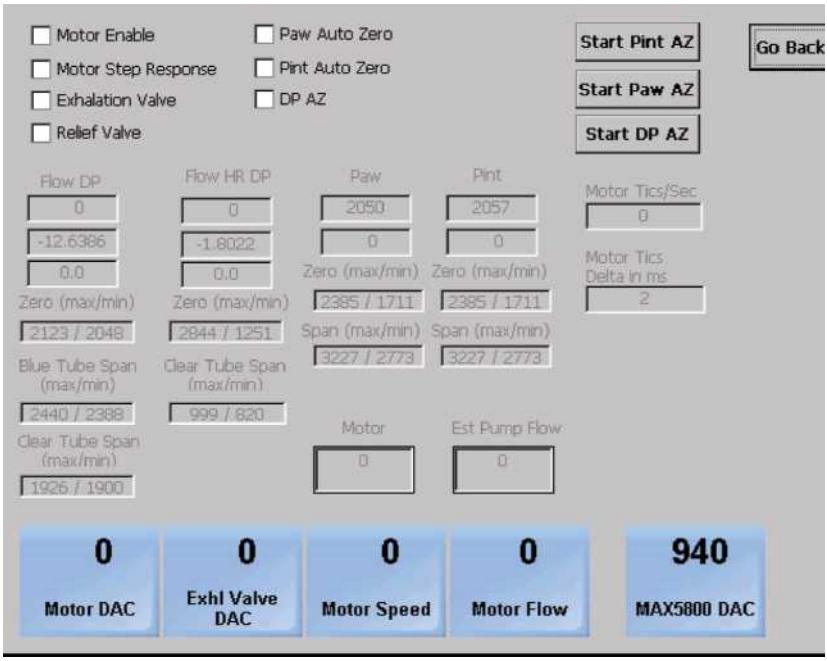


Figure 6.8 – Motor Control Screen for HT70 Plus and HT70-2

6) Use the touch screen to activate and deactivate each item below to verify operation:

- Exhalation Valve – Listen for the solenoid click
- Relief Valve – Listen for the solenoid to click
- Paw and Pint Auto Zero - Listen for the solenoid to click for each
- Start Paw AZ, Start DP AZ and Start Pint AZ – Listen for the solenoid to click for each

Pressure Relief Valve Test

1) Continue in the Service screen for the Pressure Relief Valve Test.

2) Select 'Motor Speed' and use ▲Up/▼Down to enter 200 RPM. Press Accept.

3) Select 'Relief Valve' to activate the valve.

4) Select 'Motor Enable' to activate the motor.

5) After the motor starts, use the blue cap (CAP100P) to block the gas outlet.

   a) Verify the internal pressure increases between 80 - 125 cmH_2O (displayed on the screen area "Pint cmH_2O"). Record the value on the Test Record.

b) Verify all air leakage must be from the pressure relief valve.

6) Select the 'Enable Motor' to deactivate the motor.

7) Remove the blue cap.

Pressure Verification Test

1) Continue in the Service screen for the Pressure Verification Test.

2) Attach the breathing circuit to the ventilator and connect the T-connector from a calibrated pressure analyzer to the patient connection.

3) Use the 2 blue caps to block the end of the breathing circuit and also block the outlet on the exhalation valve to close the system and allow the pressure to build.

4) Select 'Motor Enable'.

5) Verify the internal (Pint) and airway pressure (Paw) display and the external pressure analyzer are within 10% of each other. Record the values on the Test Record.

6) Select the 'Enable Motor' again to deactivate the motor.

7) Reset the 'Motor Speed' to 0 and press Accept.

8) Remove the blue caps.

System Leak Test

1) Continue in the Service screen for the System Leak Test.

2) Connect the flow monitor to the Main Flow Outlet

3) Set the Motor Flow to 30 Lpm and press Accept.

4) Remove the air inlet filter cover and filter.

5) Completely block the inlet air for more than 3 seconds and measure the flow.

6) Select 'Motor Enable'.

7) Verify the flow is less than 1 Lpm. Record the results on the Test Record.

8) Select the 'Enable Motor' again to deactivate the motor.

9) Reinstall the air inlet filter and cover.

Flow Measurement

1) Continue in the Service screen for the Flow Measurement Test.

2) Connect the flow monitor between the Main Flow Outlet and the breathing circuit.

3) Select 'Relief Valve' to activate the valve. A check mark will be displayed to verify activation.

4) Select 'Motor Enable'.
   a) Verify the measured flow is between 25.5 and 34.5 Lpm.

   b) Record the value on the Test Record.

5) Set Motor Flow to 60 Lpm and verify the measure flow is between 51 to 69 Lpm.

6) Select the 'Motor Enable' again to deactivate the motor.

7) Exit the Service Screen.

   a) Press and hold the On/Off Switch until the system shuts down (approximately 20 seconds).

   b) Press the Alarm Silence button to deactivate the alarm.

Emergency Intake Valve Test

1) With the ventilator off, attach a test lung (LNG600P) to the Main Flow Outlet.

   Note: Test lung needs to be deflated and squeezed before connecting to the HT70.

2) Verify air can be pulled through the emergency intake valve by gently squeezing the test lung and creating a negative effort (vacuum) in the HT70.

3) Remove the test lung

Patient Effort Indicator Test

1) Power up the ventilator with Standard Test Settings and attach breathing circuit and test lung (LNG600P) with an Rp20.

2) Touch the “Start Ventilation” on the touch screen.

3) Set RR to1 b/min and trigger breaths by squeezing the test lung hard enough to create a negative pressure equal to or greater than 1 cmH_2O/mbar.

   Note: Negative efforts are displayed by a yellow bar on the graph.

4) Verify the Patient Effort Indicator (on touch screen) blinks and the ventilator delivers a mandatory breath every successful squeeze of the test lung.

5) Set RR to 10 b/min, PEEP to Off, and Ptrig to 0.2 cmH_2O/mbar.

   a) Verify that there is no auto-triggering by looking at RR monitor and Patient Effort indicator.

6) Change the settings to SPONT mode with Pressure support set at 10 and Ptrig to 1 cmH_2O.

7) Trigger a breath by squeezing the test lung, and verify the ventilator delivers pressure support breaths.

Pressure Control and PEEP Test

1) Set the ventilator to Standard Test Settings (STS) except for the following: RR 10, i-Time 3.0, and P_{trig} 5.0.

2) Attach the calibration analyzer inline with the patient circuit and the test lung (LNG600P) with airway restrictor (Rp20).

3) Set PC 15 and PEEP 3.

   a) Verify the ventilator monitored Peak pressure is within ±2 cmH_2O and the PEEP is within ±1 cmH_2O of the measured pressures.

4) Set PC 15 and PEEP 5.

   a) Verify the ventilator monitored Peak pressure is within ±2 cmH_2O and the PEEP is within ±2 cmH_2O of the measured pressures.

5) Set PC 30 and PEEP 15.

   a) Verify the ventilator monitored Peak pressure is within ±3 cmH_2O and the PEEP is within ±2 cmH_2O of the measured pressures.

Note: The inspiratory pressure shall be maintained during entire inspiration time. To verify this watch the bar graph on the monitor.

6) Record the results on the Test Record.

FiO_2 Verification Test

1) Set the ventilator to Standard Test Settings, with PEEP set to 2 cmH_2O, and connect the test lung (LNG600P) with an Rp20.

2) Attach the oxygen analyzer to the Main Flow Outlet on the HT70 with a T-Adapter in-line with your breathing circuit.

3) Attach the HT70 Low Flow Reservoir to the Fresh Gas Inlet port and the flow meter hose to the oxygen source.

4) Start ventilation and allow the several breaths to be delivered at each to ensure stable readings. Record the Displayed and Measured values on the Test Record

a) Set flow meter to 3 LPM, Verify both the HT70 and Calibrated O2 analyzer are within 3% of each other.
b) Set flow meter to 5 LPM, Verify both the HT70 and Calibrated O2 analyzer are within 3% of each other.

5) Turn off the oxygen source, disconnect the Low Flow Reservoir from the HT70.

Volume Control Test

1) Set the ventilator to Standard Test Settings and connect the test lung (LNG600P) with an Rp20.

2) Place the PTS2000 Certifier FA analyzer at the gas outlet in order to measure the tidal volume. Wait for measurements to stabilize.

Note: Be sure the analyzer is set to measure using the ATP (Ambient Temperature and Pressure) parameters.

3) Set the following parameters and record the values on the Test Record.

a) VT 200 mL / Flow 30 / iTime 0.4 s / RR 10 bpm. Spec: 180 – 220 mL.

b) VT 500 mL / Flow 50 / iTime 0.6 s / RR 10 bpm. Spec: 450 – 550 mL.

4) Connect the expiratory flow sensor to the circuit and record the values on the Test Record (only for HT70 Plus Units)

a) VT 200mL / Flow 30 / iTime 0.4s / RR 10 bpm. Spec: 180 – 220 mL.

b) VT 500mL / Flow 50 / iTime 0.6s / RR 10 bpm. Spec: 450 – 550 mL.

Note: For best results when testing with flow sensor, please ensure that a 6 inch extension is used between the flow sensor and the test lung.

Manual Inflation Test

1) Set ventilator to the Standard Test Settings. Set RR to 1. Press, hold and release the Manual inflation button.

2) Verify that a manual inflation occurs each time the manual inflation button is pressed. Verify inflation is terminated when the button is released. Set RR to 15.

3) Record the results on the Test Record.

Pressure Alarm Test

Note: All activated alarms trigger an audible tone, visual LED indicators, and a displayed message.

1) Set the ventilator per Standard Test Settings (STS).

2) Set high pressure alarm 10 cmH_2O.

a) Verify the High Pressure alarm is activated.

b) Verify the Red LED indicators are activated.

c) Verify the message ‘High Pressure’ is displayed.

d) Reset the High Pressure Alarm setting to 99 cmH_2O.

3) Set the low pressure alarm 2 cmH_2O higher than the displayed Peak Paw.

a) Verify the Low Pressure alarm is activated.

b) Verify the Red LED indicators are activated.

c) Verify the message ‘Low Pressure’ is displayed.

4) Return the alarm settings to the STS.

5) Disconnect the individual limbs of the patient circuit and verify the appropriate alarm is activated.

a) Remove the Proximal Line tube and verify the ‘Check Circuit’ or ‘Prox Line’ alarm is activated.

i) Reconnect the tube and verify the alarm is cleared.

b) Remove the Exhalation Valve tube and verify the ‘Low Pressure’ is activated.

i) Reconnect the tube and verify the alarm is cleared.

c) Remove the Gas Output tube and verify the ‘Check Circuit’ or ‘Prox Line’ alarm is activated.

i) Reconnect the tube and verify the alarm is cleared.

6) Block the exhalation valve completely to trigger an ‘Occlusion’ Alarm.

a) Verify the ventilator audible alarm is activated.

b) Verify the Red LED indicators are activated.

c) Verify the message ‘Circuit Occlusion’ is displayed and the pressure does not rise.

d) Continue to block the exhalation valve and verify the message ‘Sustained Occlusion’ is displayed and the relief valve opens in approximately 10 seconds.

e) Unblock the exhalation valve and verify the alarm is cleared.

7) Press the ‘Alarm/Silence Reset’ button multiple times to clear the displayed alarm history.

Integrated Battery System Check

1) Unplug the A.C. power supply.

   a) Verify the HT70 continues to ventilate.

   b) Verify the audible alarm and handle alarm indicators activate.

   c) Verify the HT70 displays 'No Ext Power / Switching to Battery Power'.

   d) Verify the battery level indicator has changed to blue and the power level indicates at least 80%.

   e) Press the Alarm Silence/Reset button to clear the alarm.

2) Remove the Power Pac battery.

   a) Verify the HT70 continues to ventilate.

   b) Verify the audible alarm activates and handle alarm indicators flash.
   c) Verify the HT70 displays 'Switching to Backup Battery'.

   d) Verify the battery level indicator changes to red and power level indicates at least 80%.

   Note: If battery power level indicates less than 80%, connect the HT70 to external power to fully charge the Integrated Battery System.

3) Reinstall the Power Pac battery.

   a) Verify the alarm clears, but the message remains.

   b) Press the Alarm Silence/Reset button to clear the alarm message.

4) Reconnect the A.C. power supply.

   a) Verify the External Power indicator activates.

5) If any alarm messages are displayed, press the Alarm Silence Reset button until all alarm messages are cleared.

Section 7:

Troubleshooting

Section 7:
Troubleshooting

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General Information

This troubleshooting guide is intended to assist a Newport Medical factory-trained and authorized technician to troubleshoot and repair the HT70 Ventilator. Although the table will be advantageous during the evaluation of the problem, all issues may not be addressed.

The guide includes Mechanical, Pneumatic and Electronic troubleshooting.

Contact the Newport Medical Technical Services Department for additional assistance.

WARNING
Hazardous voltages are present inside the ventilator. Disconnect electrical power and oxygen sources before attempting any disassembly. Failure to do so could result in injury to service personnel and/or equipment.

Table 7.1 TROUBLESHOOTING GUIDE

Problem	Potential Cause	Corrective Action
Ventilator fails the circuit check	Leaking patient circuit	Check breathing circuit for leaks and/ or proper connections
		Change the patient circuit
	Safety valve does not close	Replace the Pump Assembly
	Manifold leaks	Replace the Pump Assembly
Low proximal pressure (P_{aw}) with normal output flow	Faulty patient circuit	Check breathing circuit for leaks and/ or proper connections
	External humidifier chamber leaking	Bypass humidifier and retest. If problem is solved, inspect and adjust the external humidifier
	Pressure transducers out of calibration	Perform a complete calibration of the ventilator. Refer to section 6, Calibrations
	Faulty exhalation valve	Replace valve
	cont.	*cont.*

Problem	Potential Cause	Corrective Action
Low proximal pressure (P_{aw}) with normal output flow *cont.*	Pressure relief valve leaking	Perform the Pressure Relief Valve Check in the OVP section. If the failure persists, contact Newport Medical Technical Support for further assistance.
	Emergency intake valve leaking	Perform the Emergency Intake Valve Check in the OVP section. If the failure persists, contact Newport Medical Technical Support for further assistance.
Low proximal pressure (P_{aw}) with low output flow	Air inlet filter blocked	Replace air filter (ensure that it is checked / changed weekly).
	Internal leak (i.e. ruptured pump diaphragm, leaking check valve, etc.)	Inspect check valves. Faulty or damaged check valves require the replacement of the pump assembly. Contact the Newport Medical Technical Support for further assistance.
	Pressure relief valve leaking	Perform the Pressure Relief Valve Check in the OVP section. If the failure persists, contact Newport Medical Technical Support for further assistance.
	Emergency intake valve leaking	Perform the Emergency Intake Valve Check in the OVP section. If the failure persists, contact Newport Medical Technical Support for further assistance.
Proximal pressure increasing slowly (Device Alert alarm may or may not occur)	Blocked air inlet	Replace air inlet filter (ensure that it is checked / changed weekly).
	High FiO_2 setting with a depleted oxygen supply	Inspect oxygen source and replace if necessary If problem persists, remove the air/oxygen mixer. If the problem is resolved, replace the mixer If the problem persists, replace the pump/manifold assembly.

Problem	Potential Cause	Corrective Action
Unstable baseline	Patient circuit leak	Check patient circuit for leaks Check patient for proper connection and compliance **Note:** If using a star lumen tubing, make sure the tubing is not connected directly to the HT70
	Internal solenoid valve or valve assembly is not functioning properly	Check the internal tubes and verify all are securely connected If problem persists, perform a full system calibration If the problem persists, replace the valve that is leaking or inoperable
	Main Control Board transducers (XD1 and XD2) are not properly calibrated	Perform the Pressure Transducer Calibration
Baseline shows PEEP with no PEEP setting	Water inside exhalation valve	Disconnect exhalation drive line tubing and drain any trapped water. If problem persists, replace the exhalation valve
	Kinked or occluded exhalation tube	Check and replace if necessary
	Kinked or occluded proximal pressure tube	Check and replace if necessary
	Dirty or occluded proximal pressure inline filter	Replace the inline filter
	Contaminated check valves	Replace pump assembly
	Malfunctioning Proportional solenoid	Replace Proportional solenoid

Problem	Potential Cause	Corrective Action
Proximal pressure has slow return to baseline	Kinked or occluded proximal pressure line	Check and replace the inline proximal filter if necessary Heat Moisture Exchanger (HME) is causing resistance during exhalation . Remove or change the HME
Pump louder than normal	Large leak in the patient circuit	Check and replace patient circuit if necessary
	Internal muffler disconnected	Remove the air inlet filter and check the screws securing the muffler Remove the rear panel assembly to inspect the muffler and replace if necessary
	Pump assembly malfunction	Replace the pump assembly
Vibration noise (i.e. bezel)	Improper assembly	Inspect and tighten all screws securing the rear panel, case, and base assemblies
	Inlet air filter cover or fan filter cover loose	Inspect and tighten the screws securing the covers
Unit auto-triggers	Leak in patient circuit	Check and replace patient circuit if necessary
	Leak at patient interface	Check patient for any leaks at the cuff or mask
	Out of Calibration	Perform transducer calibration
Does not operate on backup battery	Backup battery discharged	Connect to AC and charge for at least 3 hours
	Backup battery will not charge	Replace the backup battery
	Backup battery older than two (2) years	Replace the backup battery
	Main Control Board malfunction	Replace Main Control Board

Problem	Potential Cause	Corrective Action
Does not operate on Power Pac	Power Pac discharged	Connect to AC and charge for at least 3 hours
	Power Pac will not charge	Replace the Power Pac battery
	Replace the Power Pac battery	Power Pac older than two (2) years
	Main Control Board malfunction	Replace the Main Control Board
Does not operate on AC power	Malfunctioning or damaged power supply	Replace power supply
	Main Control Board malfunction	Replace Main Control Board
	Power Pac malfunction	Replace Power Pac
Dim display No display Intermittent display	Display brightness set to low	Press the 'Brightness' button to adjust the display
	Display backlight non-functional	Replace the LCD display assembly
	Display board non-functional	Replace the display board
	SBC board non-functional	Replace the SBC board
	LCD display cable loose	Remove rear panel and case assemblies and the display board. Inspect the LCD cable for proper connection to the display
	LCD display cable has damaged wires or connector	Replace the LCD display cable

Problem	Potential Cause	Corrective Action
Touch Screen unresponsive	Loose connection	Remove the rear panel and case assemblies and inspect the cables for proper connections on the display board
	Damaged cables	Replaced the LCD display assembly
	Main Control board malfunction	Replace the Main Control board
	Single Board Computer board malfunction	Replace SBC
Indicators do not activate: Alarm/Silence Device Alert External Power Handlebar	Loose cable connection	Remove the rear panel and case assemblies and inspect the cables for proper connections on the display board
	Switch Membrane malfunction	Replace the Switch Membrane
	Switch Membrane damaged	
	Broken wires	Replace handle assembly
Buttons unresponsive	Loose cable connection	Remove the rear panel and case assemblies and inspect the cables for proper connections on the display board
	Switch Membrane malfunction	Replace the Switch Membrane
	Switch Membrane damaged	
	Display board malfunction	Replace the display board
ON / OFF Switch unresponsive	Loose cable connection	Remove the rear panel and inspect the switch cable for proper connections on the Main Control board
	Switch malfunction	Replace the Switch
	Main Control Board malfunction	Replace Main Control Board

Problem	Potential Cause	Corrective Action
Device Alert LED on	Motor Fault error Internal Pressure (Pint) error System Error	Refer to the displayed message window or Event History log for additional information
Motor Fault	Pump assembly malfunction Main Control board malfunction	Replace Pump assembly Replace Main Control board
Device Alert	Internal Pressure (P_{int}) error	Review the Event History log. If P_{int} failure is indicated, contact Newport Medical Technical Support for further assistance
System Error	Speed table calibration error Airway pressure zero calibration error Airway Pressure calibration Internal pressure zero calibration error Internal pressure calibration error Pump leak calibration error Airway (P_{aw}) auto zero error Internal (P_{int}) auto zero error FiO_2 Ambient (21%) calibration error FiO_2 100% calibration error	Review Event History log for specific error Perform the complete system calibration If the error persists, contact Newport Medical Technical Support for further assistance

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Section 8:

Diagrams and Assembly Part Lists

Section 8:

Diagrams and Assembly Part Lists

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CONTROL BOARD
XD1, AIRWAY PRESSURE
XD3, DIFFERENTIAL PRESSURE
MOTOR DRIVE
XD2, DRIVE PRESSURE
AIRWAY PRESSURE VALVE
SAFETY VALVE
AIR FILTER
AUTO ZERO VALVES
INTERNAL PRESSURE VALVE
PUMP
AIRWAY FLOW SENSOR
O2 MIXER
AIR FILTER
MUFFLER
HIGH PRESSURE RELIEF VALVE
PROPORTIONAL VALVE
EMERGENCY AIR INTAKE VALVE
O2 SENSOR
PATIENT WYE
OUTLET CHECK VALVE
MANIFOLD
ON/OFF VALVE
BACTERIA FILTER
EXHALATION VALVE
DIAPHRAGM
BREATHING CIRCUIT
CHECK VALVE,
PROPORTIONAL VALVE DRIVE CIRCUIT
ON/OFF DRIVE CIRCUIT

Diagram 8.1 - Pneumatics System

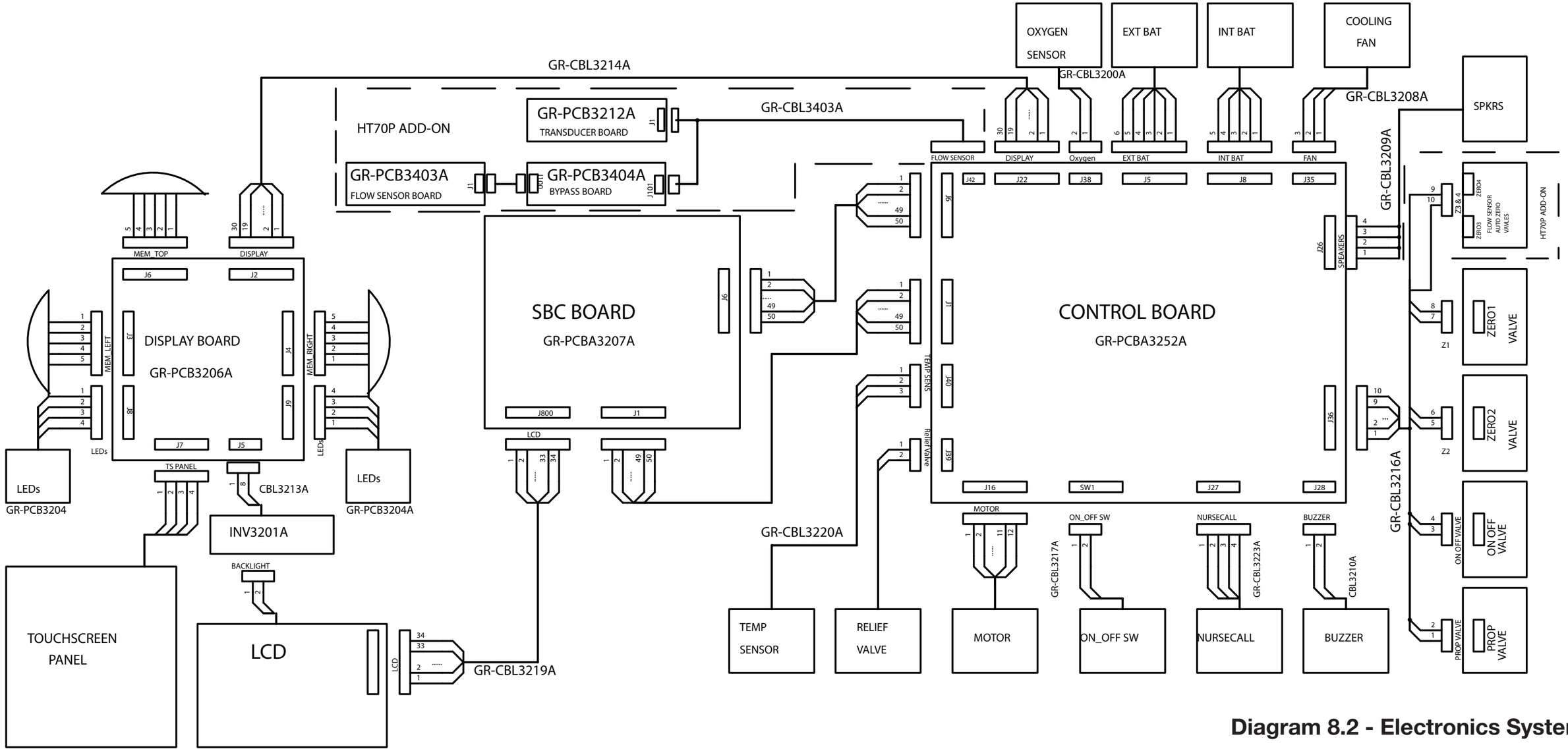
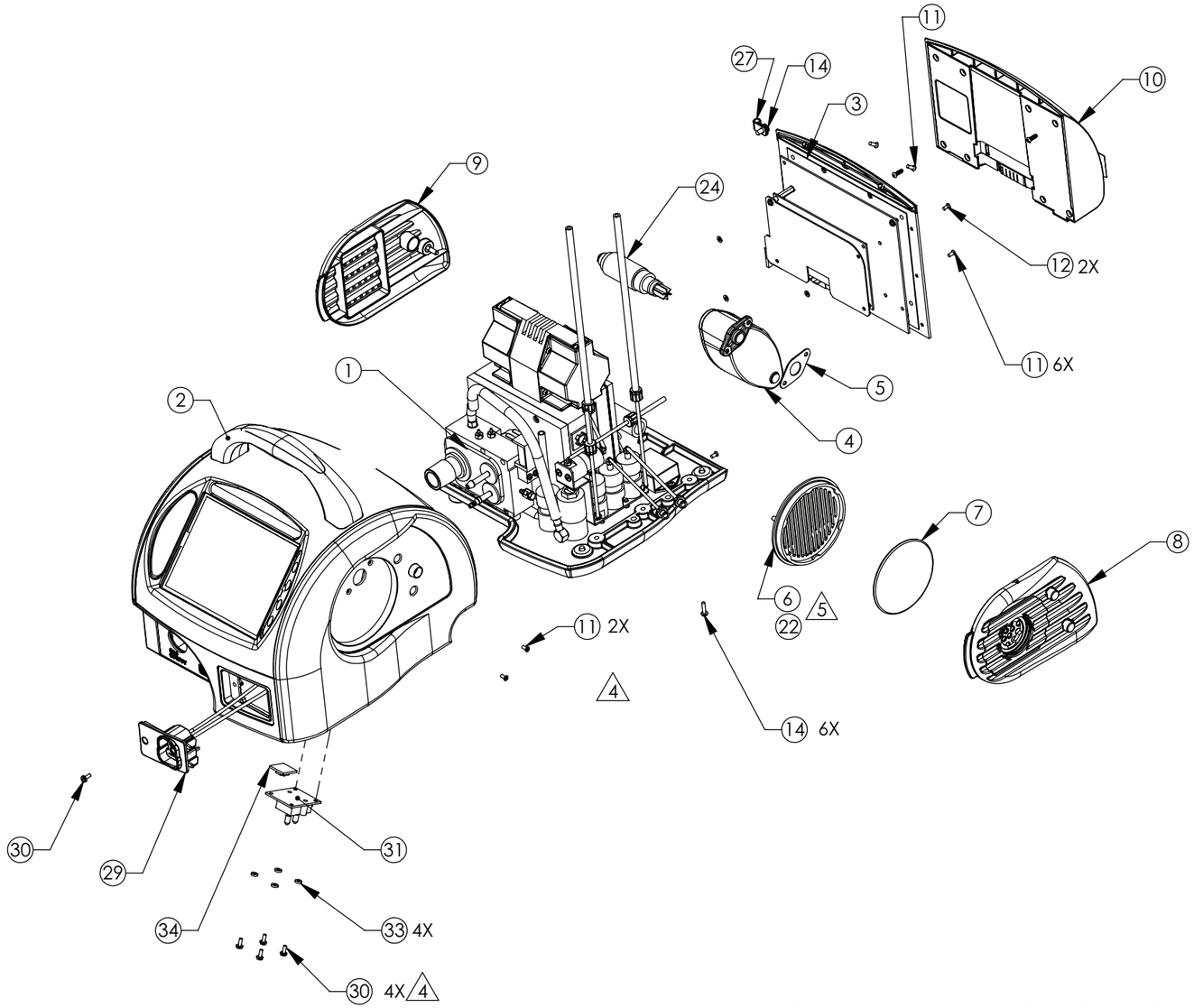


Diagram 8.2 - Electronics System



Item	Qty.	Description	Part No.
1	1	HT790 BASE ASSEMBLY W/ FLOW SENSOR, NEXT GEN	PLT3219M
2	1	HT70 CASE ASSEMBLY, NEXT GEN	GR-CVR3250A
3	1	HT7 REAR PANEL ASSEMBLY, NEXT GEN	GR-PNL3250A
4	1	ASSEMBLY, INLET MUFFLER	MUF3210A
5	1	SILICONE MUFFLER GASKET	GKT3206M
6	1	GASKET, FILTER	GKT3201M
7	1	FILTER, INLET, 80MM DIAMETER	HT460300-1
8	1	COVER INLET FILTER ASSEMBLY	CVR3215A
9	1	COVER FAN FILTER ASSEMBLY	CVR3216A
10	1	BATTERY ASSEMBLY W/ LOCKING DC CONNECTOR	BAT3271A
11	9	FLAT HEAD PHILLIPS, 300SS, 4-40 X 1/4: LG, 100DEG	SCR3210P
12	2	SCREW, 4-40 X 3/8” FLAT HEAD PHILLIPS, SST	SCR3211P
14	7	SCREW, 4-40 X 1/2” PH PAN SQ CONE SEM SS	SCR3217P
22	AR	ADHESIVE, RTV, MEDICAL GRADE	ADH110P
24	1	OXYGEN SENSOR	SEN2103P
27	1	NYLON LOOP CLAMP FOR 3/16” OD BLACK	CLP3202P
29	1	RECEPTACLE, FLOW SENSOR ASSEMBLY	GR-SEN3421A
30	5	SCREW 4-40 X 5/16” PH PAN SQ CONE SEMS SS	SCR3216P
31	1	TRANSDUCER DAUGHTER BOARD	GR-PCB321A
33	4	WASHER, FLAT, .115 ID X .250 OD X .062 THK, NYLON	WSH1020P
34	1	CABLE TIE HOLDER, 3/4” L X 3/4” W X 3/16” H	CTH100P

Diagram 8.3 - HT70 Plus Exploded View

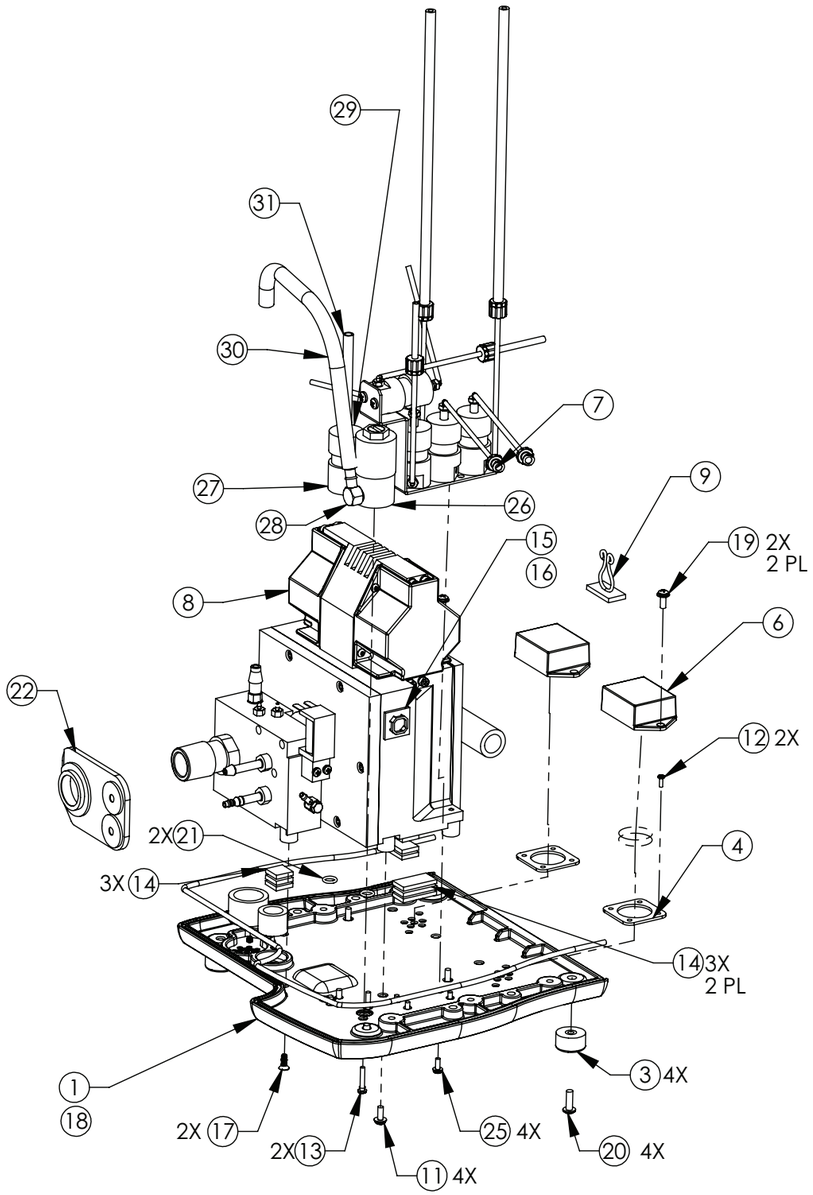
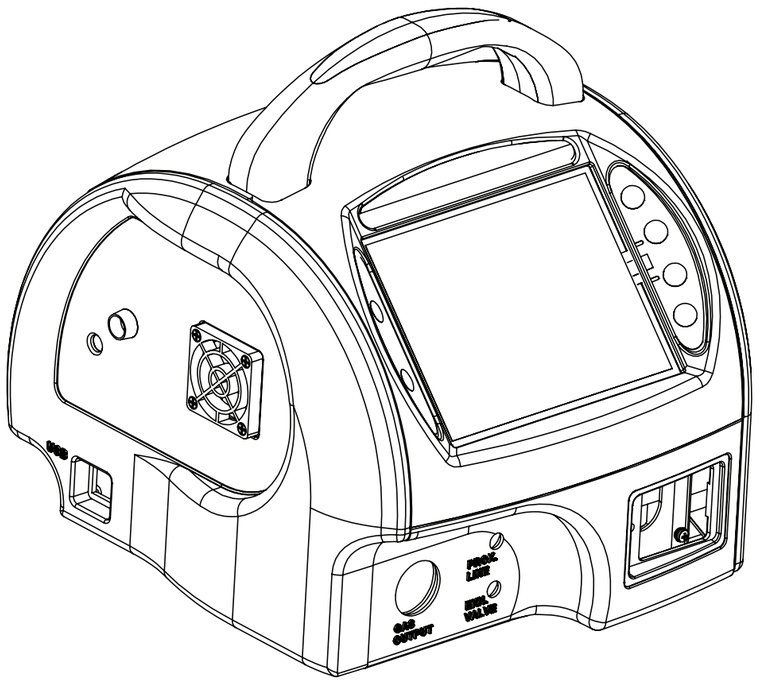


Diagram 8.4 - Base Assembly

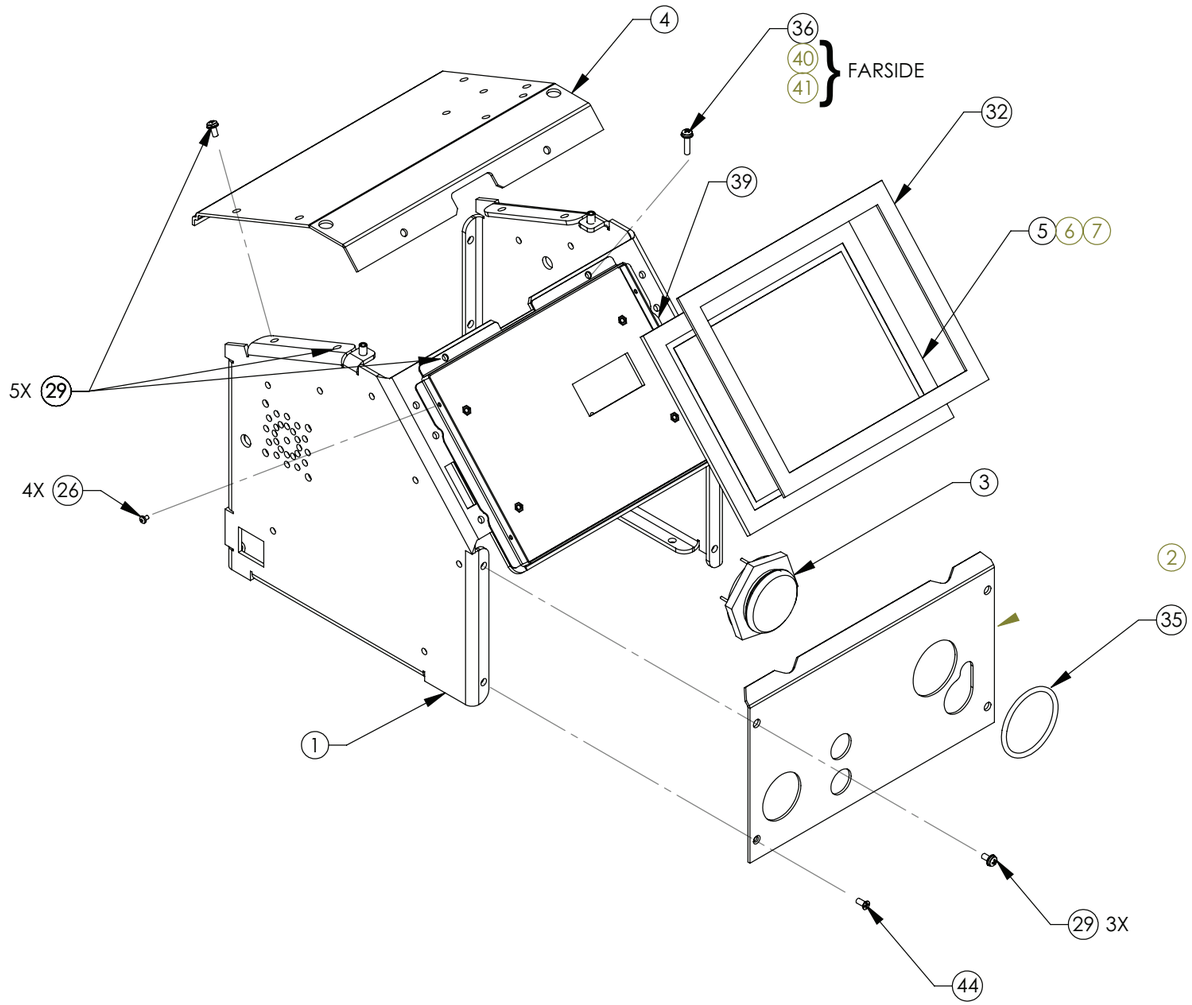
Item	Qty.	Description	Part No.
1	1	MOLDED BOTTOM PLATE	PLT3219M
2	25”	GASKET CORD., .125” OD, SILICONE SPRONGE	GKT3250P
3	4	RUBBER BUMPER W/ UNTHREADED THROUGH HOLE WITH WASHER 3/4” BASE DIA. 13/32” HEIGHT	BPR3201P
4	2	SEAL, FOAM	SEL3201M
5	1	CABLE ASSEMBLY SPEAKER CABLE	GR-CBL3209A
6	1	SOLENOID ASSEMBLY, HT70 PLUS	SOL3250A
7	1	PUMP AND MANIFOLD ASSEMBLY, NEXT GEN	GR-PMP3230A
8	1	NYLON CABLE TIE	TYR3201P
9	1	CABLE, ASSY VALVE, HT70 PLUS	GR-CBL3231A
10	6	SCREW, 6-32 X 3/8” PH PAN SQ CONE SEM SS	SCR3219P
12	4	SCREW 2-56 X .250, PAN HEAD PHIL, SST	SCP2025P
13	2	SCREW, 8-32 X 1/2 PH PAN SQ CONE SEM SS	SCR3232P
14	7.5”	SOFT SHIELD (EMI FOAM CORE GASKET) 4002, 2.7MMTHICK, 12.7M WIDE	GKT3212P
15	1	MOUNT, TIE WRAP	CTH100P
16	1	TYWRAP, SMALL	TYR100P
17	2	SCREW, 6-32 X 3/8” SELF-LOCK FLAT HEAD PHIL, SS	SCR3233P
18	A/R	ADHESIVE SEALANT	ADH108P
19	4	SCREW, 6-32 X 5/16” PH W/ ATTACHED LOCK WASHER	SCR3234P
20	4	SCREW, 8-32 X 1/2” PAN HD PHILLIPS, SST, NYLON	SCR3244P
21	2	O-RING, BUNA-N, 70A DUROMETER	ORG05307P
22	1	GASKET, PUMP MANIFOLD OUTLET	GKT3254M
23	1	GASKET SLEEVE, 1.00” OD, 0.75” ID, SILICONE	GKT3251M
24	1	GASKET SLEEVE, 0.75” OD, 0.50” ID, SILICONE	GKT3252M
25	4	SCREW, 4-40 X 5/16 PH PAN SQ CONE SEM SS	SCR3216P
26	1	SOLENOID VALVE	VLV3227M
27	1	SOLENOID VALVE, PROX.	VLV3225M
28	1	CONNECTOR 1/4” TUBE X 1/8 NPT BRASS ELBOW	CON3205P
29	1	CONNECTOR, 1/8T X 10-32M	CON200P
30	8”	TUBING, 1/4 ID X 3/8 OD CLEAR TYGON	TUB3210P
31	3.5”	TUBING, 1/8 OD X 1/4 OD	TUB300P
32	A/R	PIPE PASTE - LOX8	PPS1000P



Item	Qty.	Description	Part No.
1	1	CHASSIS	BSE3201M
2	1	COVER FRONT CHASSIS HT70+	CVR3255M
3	1	BUZZER CABLE	CBL3210A
4	1	COVER REAR	CVR3210M
5	1	DISPLAY, LCD	DSP2105P
6	1	TOUCHSCREEN	PNL3205P
7	AR	TAPE, DOUBLE COATED 1/4 WIDE	TAP078P
8	1	HOUSING, CENTER, CHASSIS	HSG3217M
9	1	HOUSING, CENTER BOTTOM, LOWER PROFILE	HSG3216M
10	1	HANDLE ASSEMBLY	GR-HDL3215A
11	1	TOP MEMBRANE SWITCH	MEM3212M
12	1	LEFT MEMBRANE SWITCH	MEM3211M
13	1	RIGHT MEMBRANE SWITCH	MEM3210M
14	1	HOUSING, AIR INTAKE SIDE	HSG3223M
15	1	FAN INTAKE FILTER KIT	FLT3202P
16	1	CABLE ASSY, FAN	GR-CBL3208A
17	1	HOUSING, ACCESSORY SIDE	HSG3222M
18	1	BATTERY, INTERNAL	BAT3205A
19	4.5”	GASKET, EMI SHIELDING	GKT3214M
20	4	GASKET, CLOSED CELL, DOUBLE SIDED, 3/4” W, 0.125” THICK, E150	GKT4408P
21	1	BRACKET, BATTERY	BKT3214M
22	1	CABLE, LCD DATA	GR-CBL3219A
23	1	“E” CLAMP, 1/4 HOLDING DIAMETER	CLP2102P
24	1	HT70 DISPLAY BOARD WITH EXTERNAL INVERTER	GR-PCB3206A
25	1	CABLE ASSY, DISPLAY TO CONTROL PCB, RIBBON	GR-CBL3214A
26	4	SCREW, M2 X 0.4 X 3MM, PAN HD PH, SST	SCR2133P
27	4	FLAT HD PHILLIP, T8-8 SS, 4-40, 7/16” LG	SCR3213P
28	23	SCREW 4-40 X 5/16” PH PAN SQ CONE SEMS SS	SCR3216P
29	17	SCREW 4-40 X 1/4” PH PAN SQ CONE SEMS SS	SCR3215P
30	2	SCREW, 4-40 X 3/4” PAN HD, PATH	SCR3277P

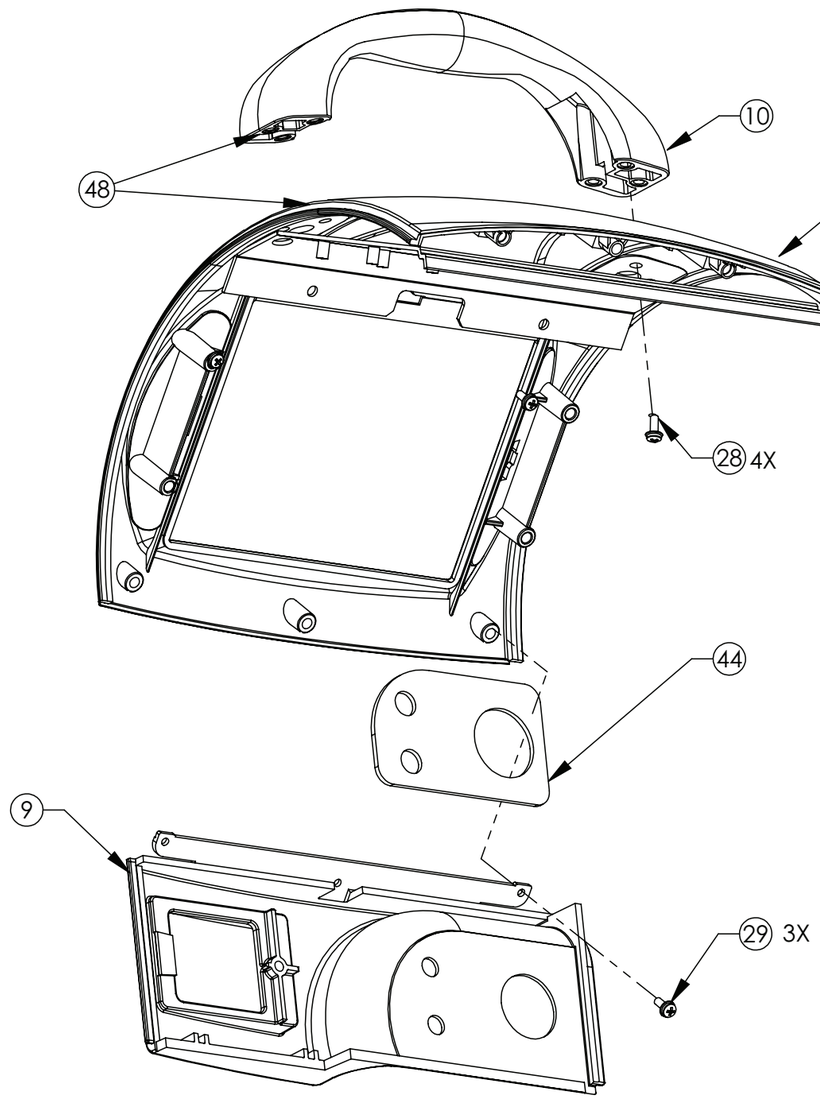
Item	Qty.	Description	Part No.
31	4	WASHER, ID .115 TO .130, OD .240 TO .290, SST	WSH1512P
32	1	GASKET, LCD	GKT3208M
33	AR	ADHESIVE, CLEAR TWO PART	ADH111P
34	1	O-RING, SILICONE 1 1/4 ID X 1 7/16 OD	ORG3216P
35	1	SCREW, 4-40 X 1/2 PH PAN SQ CONE SEM SST	SCR3217P
36	11”	TAPE, KAPTON POLYMIDE, 1/2’	TAP077P
37	3	WASHER, SPRING LOCK #4, 18-8 SST	WSH3207P
38	1	HEX NUT, 4-40 THD, 3/16” W, 1/16” H, SST	NUT2107P
39	4	SCREW, 4-40 X 11/16” PH PAN, 18-8 SST	SCR3218P
40	1	SCREW, 4-40 X .25”, 100 DEG FLAT HEAD PHILLIPS, 300 S	SCR3210P
41	6”	GASKET, 1/4 X 3/4 ADHESIVE BACKED FOAM	GKT3209P
42	1	MICROSEMI BACKLIGHT INVERTER	INV3201A
43	1	CABLE BACKLIGHT INVERTER	CBL3213A
44	1	GASKET, HOUSING CENTER BOTTOM	GKT3253M
45	1	COVER, USB CUTOUT	CVR3256M
48	AR	ADHESIVE, RTV SEALANT	ADH108P
49	3”	GASKET CORD, .125 OD SILICONE SPONGE	GKT3250P

Diagram 8.5 - HT70 Plus Case Assembly (1 of 7)



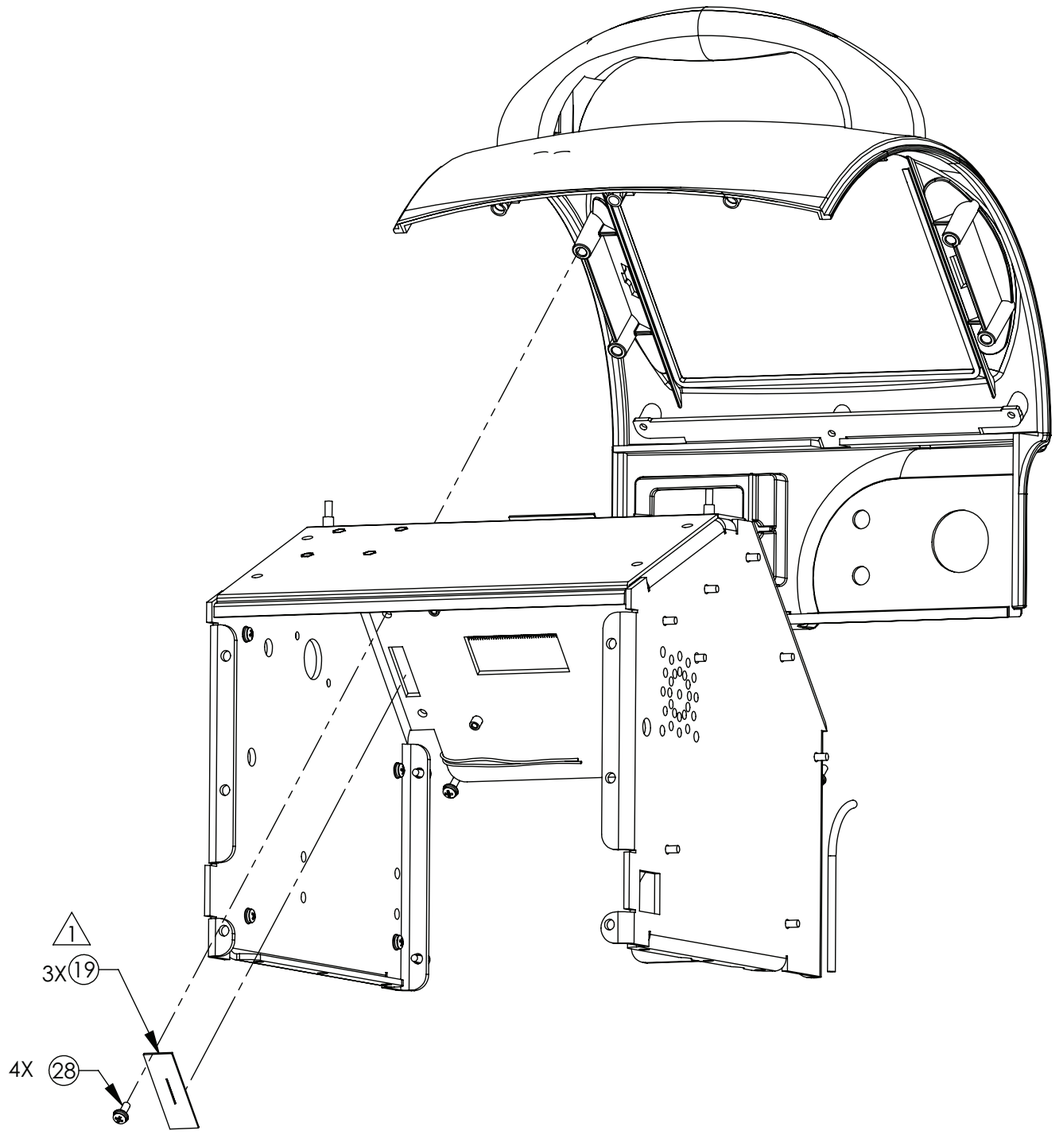
Item	Qty.	Description	Part No.
1	1	CHASSIS	BSE3201M
2	1	COVER FRONT CHASSIS HT70+	CVR3255M
3	1	BUZZER CABLE	CBL3210A
4	1	COVER REAR	CVR3210M
5	1	DISPLAY, LCD	DSP2105P
6	1	TOUCH SCREEN	PNL3205P
7	1	TAPE, DOUBLE COATED 1/4 WIDE	TAP078P
26	4	SCREW, M2 X 0.4 X 3MM, PAN HD PH, SST	SCR2133P
28	1	SCREW 4-40 X 5/16”, PH PAN SQ CONE SEMS SS	SCR3216P
29	7	SCREW 4-40 X 1/4”, PH PAN SQ CONE SEMS SS	SCR3215P
32	1	GASKET, LCD	GKT3208M
34	1	O-RING, SILICONE 1 1/4 ID X 1 7/16 OD	ORG3216P
35	1	SCREW, 4-40 X 1/2 PH PAN SQ CONE SEM, SST	SCR3217P
36	2 IN	TAPE, KAPTON, POLYMIDE, 1/2”	TAP077P
37	1	WASHER, SPRING LOCK #4, S.S.	WSH3207P
38	1	NUT, HEX 4-40 THD, S.S.	NUT2107P
40	1	SCREW, 4-40 X .25”, 100 DEG FLAT HEAD PHILLIPS, 300 SS	SCR3210P

Diagram 8.5 - HT70 Plus Case Assembly (2 of 7)



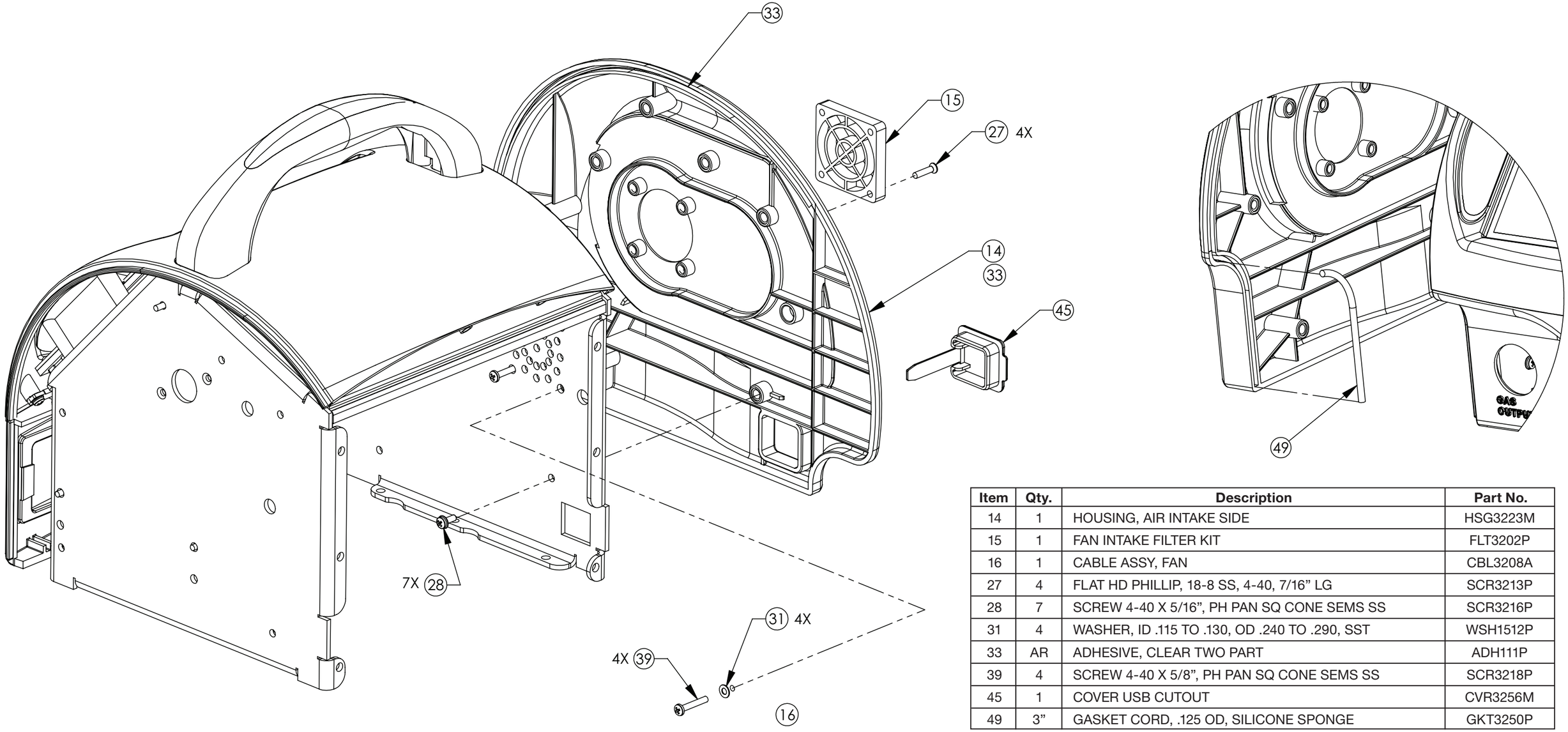
Item	Qty.	Description	Part No.
8	1	HOUSING CENTER, CHASSIS	HSG3217M
9	1	HOUSING, CENTER BOTTOM, LOWER PROFILE	HSG3216M
10	1	HANDLE ASSEMBLY	HDL3215A
28	4	SCREW 4-40 X 5/16” PH PAN SQ CONE SEMS SS	SCR3216P
29	3	SCREW 4-40 X 1/4” PH PAN SQ CONE SEMS SS	SCR3215P
33	AR	ADHESIVE, CLEAR TWO PART	ADH111P
44	1	GASKET, HOUSING CENTER BOTTOM	GKT3253M
48	AR	ADHESIVE, RTV SEALANT	ADH108P

Diagram 8.5 - HT70 Plus Case Assembly (3 of 7)



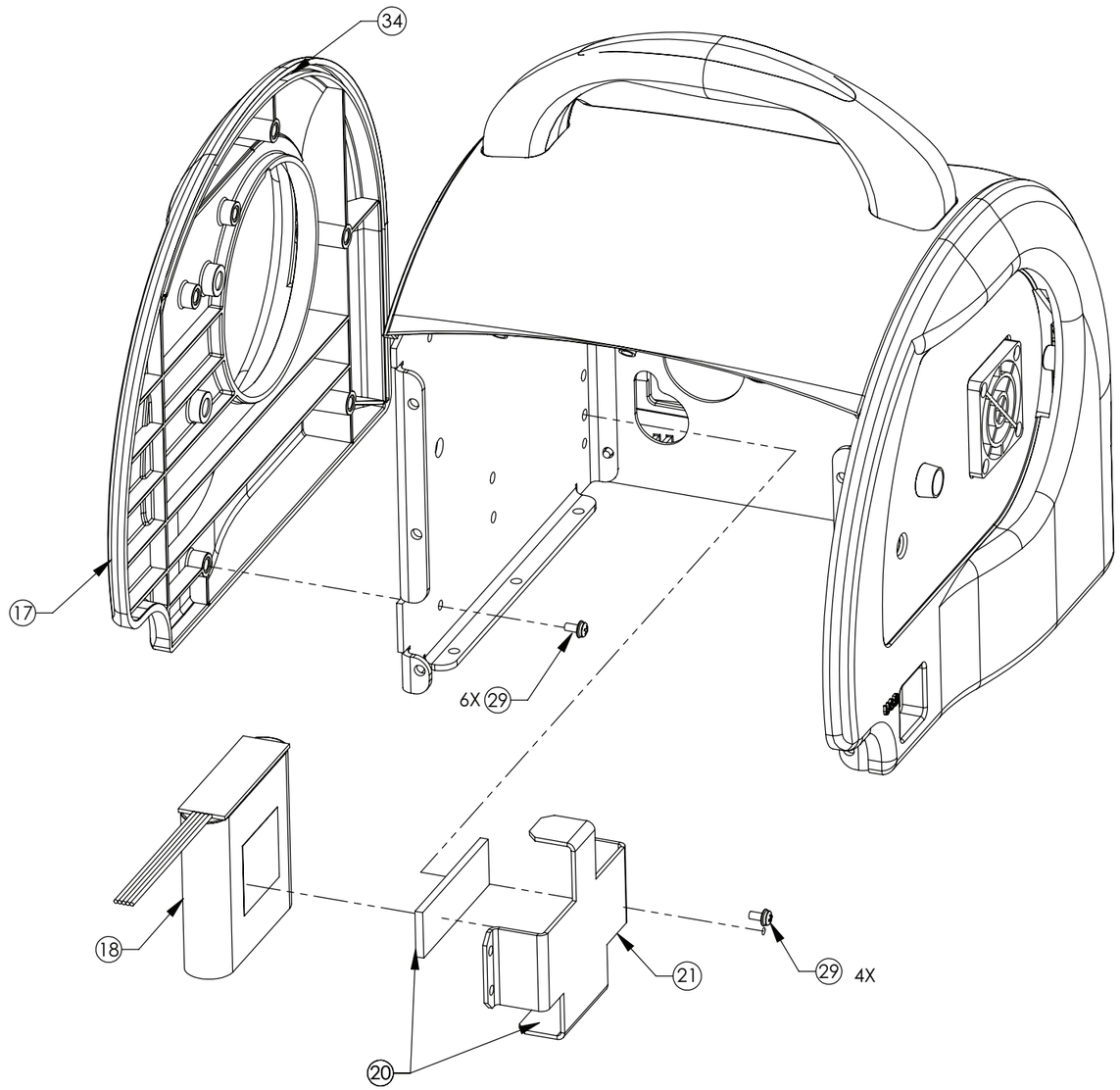
Item	Qty.	Description	Part No.
19	4.5”	GASKET, EMI SHIELDING	GKT3214M
28	4	SCREW 4-40 X 5/16’ PH PAN SQ CONE SEM SS	SCR3216P
36	9 IN	TAPE, KAPTON POLYMIDE, 1/2”	TAP077P

Diagram 8.5 - HT70 Plus Case Assembly (4 of 7)



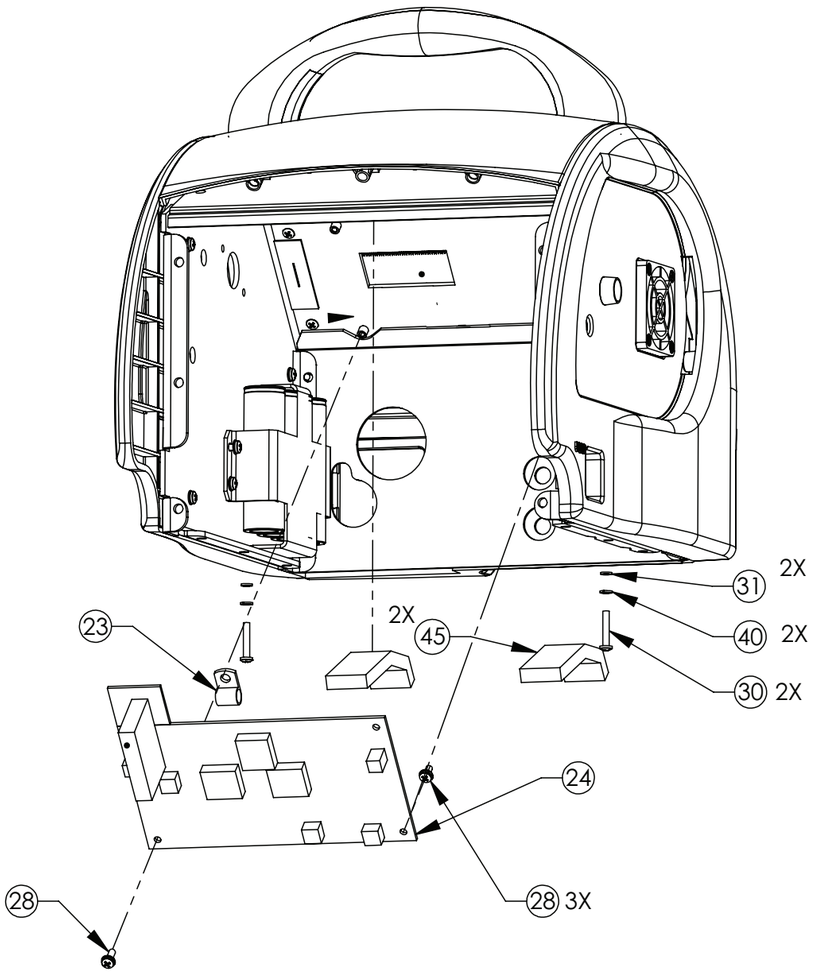
Item	Qty.	Description	Part No.
14	1	HOUSING, AIR INTAKE SIDE	HSG3223M
15	1	FAN INTAKE FILTER KIT	FLT3202P
16	1	CABLE ASSY, FAN	CBL3208A
27	4	FLAT HD PHILLIP, 18-8 SS, 4-40, 7/16” LG	SCR3213P
28	7	SCREW 4-40 X 5/16”, PH PAN SQ CONE SEMS SS	SCR3216P
31	4	WASHER, ID .115 TO .130, OD .240 TO .290, SST	WSH1512P
33	AR	ADHESIVE, CLEAR TWO PART	ADH111P
39	4	SCREW 4-40 X 5/8”, PH PAN SQ CONE SEMS SS	SCR3218P
45	1	COVER USB CUTOUT	CVR3256M
49	3”	GASKET CORD, .125 OD, SILICONE SPONGE	GKT3250P

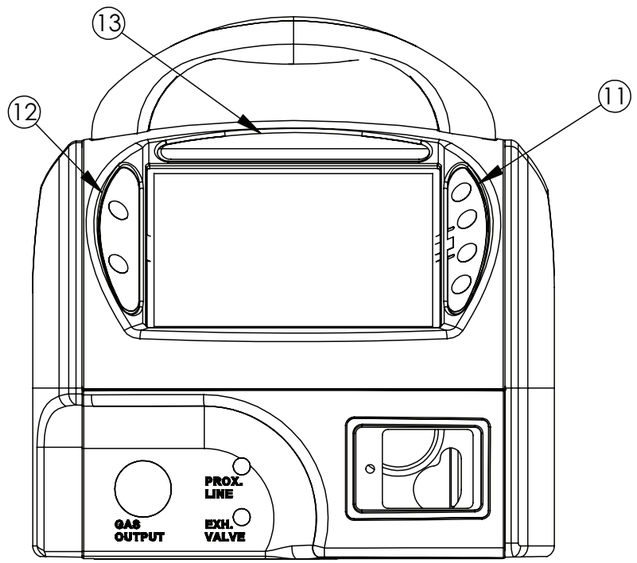
Diagram 8.5 - HT70 Plus Case Assembly (5 of 7)



Item	Qty.	Description	Part No.
17	1	HOUSING, ACCESSORY SIDE	HSG3222M
18	1	BATTERY, INTERNAL	BAT3205A
20	3	GASKET, CLOSED CELL, DOUBLE SIDED, 3/4" W, 0.125 THICK, E150	GJT4408P
21	1	BRACKET, BATTERY	BKT3214M
28	6	SCREW 4-40 X 5/16" PH PAN SQ CONE SS	SCR3216P
29	4	SCREW 4-40 X 1/4' PH PAN SQ CONE SS	SCR3215P
33	AR	ADHESIVE, CLEAR TWO PART	ADH111P

Diagram 8.5 - HT70 Plus Case Assembly (6 of 7)





Item	Qty.	Description	Part No.
11	1	TOP MEMBRANE SWITCH	MEM3212M
12	1	LEFT MEMBRANE SWITCH	MEM3211M
13	1	RIGHT MEMBRANE SWITCH	MEM3210M
22	1	CABLE, LCD DATA	CBL3219A
23	1	“E” CLAMP, 1/4 HOLDING DIAMETER	CLP2102P
24	1	HT70 DISPLAY BOARD WITH EXTERNAL INVERTER	PCB3206A
25	1	CABLE ASSY, DISPLAY TO CONTROL PCB, RIBBON	CBL3214A
28	1	SCREW 4-40 5/16” PH PAN SQ CONE SEMS SS	SCR3216P
29	3	SCREW 4-40 1/4” PH PAN SQ CONE SEMS SS	SCR3215P
30	2	SCREW 4-40 X 3/4 PAN HD, PATCH	SCR3277P
31	2	WASHER, ID .115 TO .130 OD .240 TO .290 SST	WSH1512P
37	3	WASHER, SPRING LOCK #4, 18-8 SST	WSH3207P
38	1	HEX NUT, 4-40 THD, 3/16” W, 1/16” H, SST	NUT3207P
41	6”	GASKET, 1/4 X 3/4 ADHESIVE BACKED FOAM	GKT3209P

Diagram 8.5 - HT70 Plus Case Assembly (7 of 7)

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